

Optimisation of orthopaedic implant design using statistical shape space analysis based on level sets

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Abstract

Statistical shape analysis techniques have shown to be efficient tools to build population specific models of anatomical variability. Their use is commonplace as prior models for segmentation, in which case the instance from the shape model that best fits the image data is sought. In certain cases, however, it is not just the most likely instance that must be searched, but rather the whole set of shape instances that meet certain criterion. In this paper we develop a method for the assessment of specific anatomical/morphological criteria across the shape variability found in a population. The method is based on a level set segmentation approach, and used on the parametric space of the statistical shape model of the target population, solved via a multi-level narrow-band approach for computational efficiency. Based on this technique, we develop a framework for evidence-based orthopaedic implant design. To date, implants are commonly designed and validated by evaluating implant bone fitting on a limited set of cadaver bones, which not necessarily span the whole variability in the population. Based on our framework, we can virtually fit a proposed implant design to samples drawn from the statistical model, and assess which range of the population is suitable for the implant. The method highlights which patterns of bone variability are more important for implant fitting, allowing and easing implant design improvements, as to fit a maximum of the target population. Results are presented for the optimisation of implant design of proximal human tibia, used for internal fracture fixation.

Key words: Statistical shape models, image registration, principal component analysis, level sets, orthopaedics, implant design

1 Introduction

Statistical shape analysis techniques have shown to be efficient tools to build population specific models of anatomical variability. Their flagship, the Active Shape Model (ASM), proposed by Cootes et al. (1995) provides a method to study the variability encountered across a population in a compact representation based on a decomposition via principal components analysis (PCA) (Bishop, 1995). Statistical shape models representing the variation of shape and gray-level appearance, namely Active Appearance Models (AAM) (Cootes et al., 2004; Cootes and Taylor, 2004), have been extensively used in image segmentation to locate structures of interest and to solve many medical image interpretation problems. For instance, they have been used to locate vertebrae in DXA images of the spine (Cootes and Taylor, 2004; Roberts et al., 2006; Smyth et al., 1996), structures in MR images of the brain (van Ginneken et al., 2002; Hill et al., 1994), the femoral head in MR images (Cootes and Taylor, 2004), the prostate in MR images (Haslam et al., 1994), and the outlines of ventricles of the heart in echocardiograms (Hill et al., 1994; Mitchell et al., 2000), amongst others. A comprehensive review of statistical shape models for 3D medical image segmentation is given by Heimann and Meinzer (2009). More recently, statistical shape models have been used for shape estimation in image-free computer assisted surgery (Rajamani et al., 2007).

In all these applications, the approach is to find the instance in the statistical shape model that best approximates the input data, subject to some regularisation constraints (Davies et al., 2002; Rajamani et al., 2007). Optimisation in shape space of more complex criteria based on clinically meaningful shape measures related to anatomical locations has not been fully explored. Sierra et al. (2006) formulate a minimisation process based on Lagrange multipliers to incorporate such additional constraints, and then optimise this criterion based on a gradient descent algorithm starting from the mean of the shape distribution. This is used in their application to generate virtual anatomical models for surgery simulation, instantiated by specifying clinical parameters, such as fundus/cervix length/width, that depend non-linearly on the shape coefficients. However, it is not guaranteed that their optimisation algorithm will produce the instance of the shape space that best meets the constraints. Further, in common to other existing works, the aim is to find a single instance from the statistical shape model as the solution to their problem. In certain cases, it may be interesting to find *all* instances of the shape model that meet

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69 a certain criterion. That is, one may be interested in estimating which range
70 of the population falls within a given anatomical criterion, thus establishing
71 a partition of the shape space into “valid” and “invalid” shapes.

72 In this work our aim is to develop a framework to evaluate a given anatomi-
73 cal/morphological criterion across the full PCA shape space, in order to find
74 the group of shape instances that satisfy the criterion. The method is based on
75 level sets on the parametric domain of the shape coefficients. Level set methods
76 define a powerful optimisation framework that, in combination with statistical
77 shape priors, has been used to recover objects of interest by the propagation
78 of curves or surfaces (Bresson et al., 2006; Chen et al., 2002; Cremers, 2006;
79 Leventon et al., 2000; Rousson et al., 2004). However, these previous works
80 are of a very different nature to ours, as they deal with the extraction of
81 structures of interest in medical images, employing level sets as their choice
82 of shape representation. The shape prior is thus defined as a PCA of levels
83 set representations, and the segmentation method finds the most likely shape.
84 In our case, we do not employ level sets as a shape modelling tool, but as an
85 optimisation framework to assess complex criteria in PCA space. The level
86 set is therefore defined in the parametric shape coefficient space, not in image
87 space. The high dimensionality of level sets allows for the segmentation of the
88 space of any dimension, determined by the number of principal components
89 retained. Moreover, the ability to represent complex topologies can be used to
90 identify disconnected subsets of the shape space that meet the criterion.

91 The ultimate goal of an orthopaedic implant is to stabilise the fractured bone,
92 to enable fast healing of the injured bone, and to return early mobility and full
93 function of the injured extremity. These aspects are related to the shape of the
94 implant, its material and the mechanical response it produces to decrease the
95 stress at the fracture site. Although these three aspects should be considered
96 when designing an orthopaedic implant, in this work we focus on the shape of
97 the implant, and its ability to fit to the bone surface. Mechanical and material
98 aspects are out of the scope of the presented study, although some comments
99 about mechanical considerations are included in the conclusions section.

100 Current practice in orthopaedic research involves the evaluation of implants for
101 fracture fixation by manual fitting and fixation procedures, applied on a small
102 set of cadaver bones in a trial-and-error process to find the optimal implant
103 shape and position (Goyal et al., 2007). More recently, a noninvasive semi-
104 automatic method for quantifying implant fitting was developed (Schmutz
105 et al., 2008). Although the authors discussed recommendations for optimising
106 fitting, there are no real results on how these modifications would improve the
107 fitting. Moreover, the method was tested on a small set of 21 CT data sets.
108 Using limited amount of CT data or cadaver specimens does not necessarily
109 describe the diversity in a population, such as age, gender or ethnic origin.
110 This diversity can be studied using statistical shape analysis techniques. In this

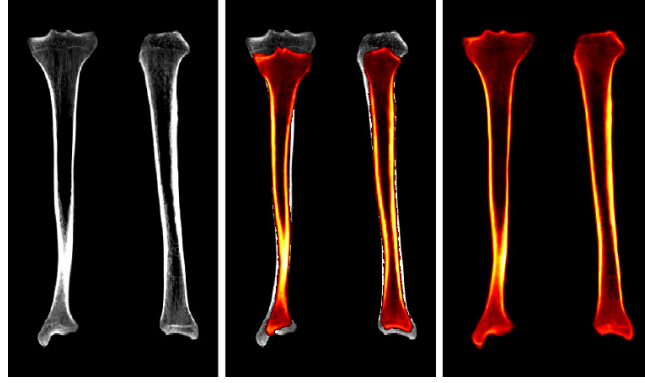


Fig. 1. Image registration. CT slice of the left human tibia, chosen as a reference bone; overlay of the rigid registration; overlay of the non-rigid registration matching the reference.

work, we show how our framework can be used as an evidence-based design methodology, assessing implant fitting on samples drawn from a statistical shape-and-intensity model by means of an automatic fitting procedure. We thus evaluate which proportion of the whole population is correctly fit by the proposed design. Then, by correlating segmented instances to the PCA manifold we are able to propose modifications to implant shape design as to fit a maximum of the target population.

Section 2 will briefly introduce the basic concepts behind statistical shape models based on PCA. In section 3, the key idea will be presented, that is the use of level set segmentation for PCA shape space optimisation. In section 4 we describe our framework for orthopaedic implant fitting assessment, and show results on the optimisation of the design of human tibial plates. Finally, discussion and conclusions are provided in section 5.

2 Statistical shape model

2.1 Image registration

The first step in generating a statistical model from a training set of images or shapes is to establish correspondences across the samples in the training set. Numerous approaches have been proposed in the literature, but since our aim in this paper is to construct shape-and-intensity models we will focus on non-rigid image registration techniques, and will illustrate the approach on CT images of human tibiae.

First, an image from the training set is selected as the reference, using an average box size as a reference, to which all other images will be registered.

134 In order to compensate for the different positioning during CT acquisition, we
 135 spatially align the remaining images of the training data set with the selected
 136 reference, via rigid registration. This allows to overcome the pose disparity
 137 and to maintain the size variation of the tibia (Figure 1). The next step in
 138 our model construction consists in warping the instances in the training set
 139 to the reference image. To capture the entire anatomical variability, we ap-
 140 ply an intensity-based non-rigid registration algorithm (Rueckert et al., 2001,
 141 2003). This algorithm defines the deformation as a B-spline mapping, defined
 142 by a uniformly-spaced grid of control points and the corresponding B-spline
 143 coefficients.

144 For the registration of CT data sets in our particular application, we employ
 145 sum of square distances (SSD) as the similarity metric, and gradient descent as
 146 the optimisation function. Based on the deformation fields obtained from the
 147 registration process, we build vectors of corresponding positions and image
 148 intensities. The reference image can be described as in Generalized Image
 149 Models (González et al., 2004):

$$v_R = (x_1, y_1, z_1, I_1, \dots, x_n, y_n, z_n, I_n), \quad (1)$$

150 where n is the number of voxels in the region of interest and I_i is the intensity
 151 at voxel (x_i, y_i, z_i) . Similarly, each of the other images can be described as a
 152 vector of the same length:

$$v_j = (x_1 + \Delta x_1^j, y_1 + \Delta y_1^j, z_1 + \Delta z_1^j, I_1^j, \dots, \\ x_n + \Delta x_n^j, y_n + \Delta y_n^j, z_n + \Delta z_n^j, I_n^j), \quad (2)$$

153 where $(\Delta x_i^j, \Delta y_i^j, \Delta z_i^j)$ is the displacement vector at position (x_i, y_i, z_i) , and
 154 I_i^j is the intensity of the voxel $(x_i + \Delta x_i^j, y_i + \Delta y_i^j, z_i + \Delta z_i^j)$ in image j .

155 2.2 Principal Component Analysis

156 The resulting image vectors described in Eq. (2) are high dimensional data,
 157 because we consider every point coordinate in the region of interest. To reduce
 158 the dimensionality of the data and obtain a compact parametric description,
 159 we apply principal component analysis. PCA is a multivariate factor analysis
 160 technique aiming at finding a low-dimensional manifold in the space of the
 161 data, such that the distance between the data and its projection on the mani-
 162 fold is small (Bishop, 1995). PCA is the best, in the mean-square error sense,
 163 linear dimension reduction technique.

164 Given a set of training data $\{\vec{t}_1, \vec{t}_2, \dots, \vec{t}_N\}$, with $\vec{t}_i = (\vec{x}_i, \vec{y}_i, \vec{z}_i)$ and N equal to
 165 number of training instances, PCA finds a new orthonormal basis $\{\vec{u}_1, \dots, \vec{u}_D\}$

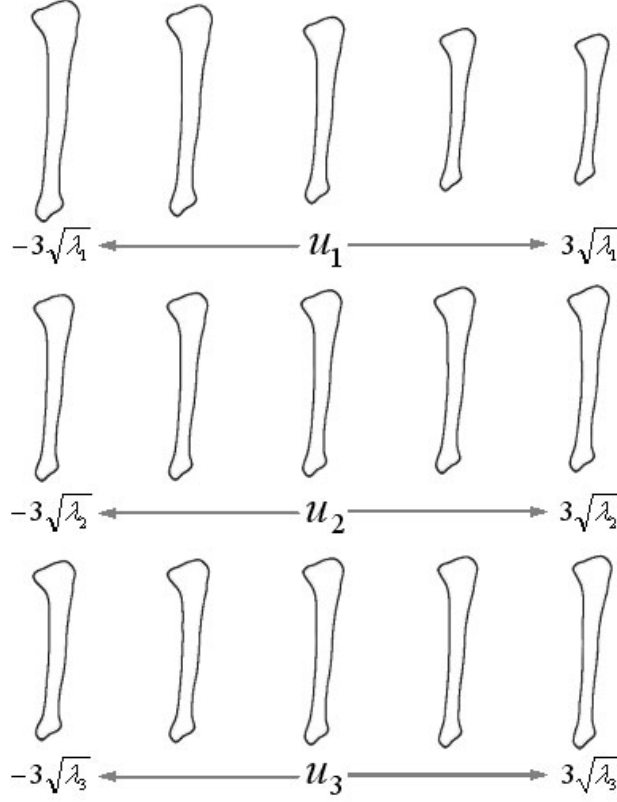


Fig. 2. The three first modes of variation for left human tibia are visualized individually. The first mode affects the change in the tibia length; the second mode influences the changes of the lateral condyle and a slight torsion of the lateral surface of the tibia; the third mode affects abduction of the medial condyle, changes of medial malleolus and in medial surface of the tibia.

166 with its axes ordered. This new basis is rotated such that the first axis is
 167 oriented along the direction in which the data has its highest variance. The
 168 second axis is oriented along the direction of maximal variance in the data,
 169 orthogonal to the first axis. Similarly, subsequent axes are oriented so as to
 170 account for as much as possible of the variance in the data, subject to the
 171 constraint that they must be orthogonal to the preceding axes. Consequently,
 172 these axes have associated decreasing “index” λ_d , $d = 1, \dots, D$, corresponding
 173 to the variance of the data set when projected on the axes. The principal
 174 components are the set of new ordered basis vectors.

The principal components are found by computing the sample covariance matrix of the data set, \vec{S} , and then finding its eigenstructure

$$\vec{S}\vec{U} = \vec{U}\vec{\Lambda}.$$

175 \vec{U} is a $D \times D$ matrix which has the unit length eigenvectors $\vec{u}_1, \dots, \vec{u}_D$ as
 176 its columns, and $\vec{\Lambda}$ is a diagonal matrix with the corresponding eigenvalues
 177 $\lambda_1, \dots, \lambda_D$. The eigenvectors are the principal components and the eigenvalues

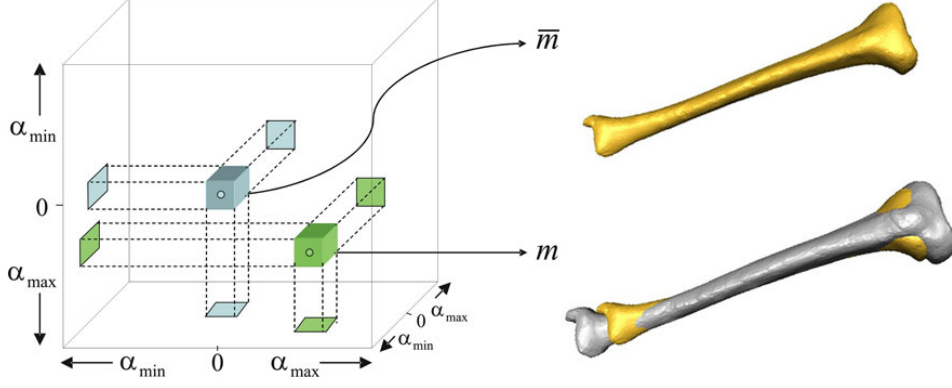


Fig. 3. Shape space defined by the three first principal components. The center element (labeled in the figure \bar{m}) corresponds to the mean of the population. Each element in this shape space is formed by a linear combination of the principal components, in this case $m = \bar{m} + \alpha_1\sqrt{\lambda_1}\vec{u}_1 + \alpha_2\sqrt{\lambda_2}\vec{u}_2 + \alpha_3\sqrt{\lambda_3}\vec{u}_3$.

178 their corresponding projected variances (Figure 2).

179 3 Optimisation in PCA space using level sets

180 3.1 PCA shape space mapping

181 Let us consider the shape space defined by the weighted linear combination of
 182 the first $L \leq D$ eigenvectors $\vec{u}_1, \dots, \vec{u}_L$ of the PCA decomposition of a set of
 183 training shapes in \mathcal{R}^D . Each element $m \in \mathcal{R}^D$ in this shape space is defined
 184 by a set of coefficients $\alpha_1, \dots, \alpha_L$ (Figure 3):

$$m = \bar{m} + \sum_{i=1}^L \alpha_i \sqrt{\lambda_i} \vec{u}_i, \quad (3)$$

185 where $\lambda_1, \dots, \lambda_L$ are the eigenvalues corresponding to each principal compo-
 186 nent, and \bar{m} is the arithmetic mean of the training sets. Now let us consider
 187 a scalar mapping $\mathcal{M} : A = [\alpha_{min}, \alpha_{max}]^L \rightarrow \mathcal{R}$. This mapping can represent a
 188 clinically meaningful anatomical criterion derived from the shapes in the PCA
 189 space (e.g. femoral inclination angle (Kozic et al., 2008)). We now would like
 190 to find all instances in the shape space that meet a certain criterion dependent
 191 on the scalar measure. This problem is approached as a segmentation in the
 192 PCA shape space defined by the mapping \mathcal{M} defined above, and solved using
 193 the level sets framework described in the following section.

Segmentation techniques based on active contours, or deformable models, have been widely used in image processing for different medical applications (Kass et al., 1987; McInerney and Terzopoulos, 1996). The idea behind active contours is to extract the boundaries of homogeneous regions within the image, while keeping the model smooth during deformation. In such models, the initial contour, specified by the user, is evolved to the boundaries of the object by balancing two energy forces. The first force, computed from image data, represents external energy that attracts the curve toward image features, while the second force, defined within the curve, represents the internal energy and affects the smoothness of the curve. A particular instantiation of this paradigm is that of active contours based on level sets (Chan and Vese, 2001; Chen and Guan, 2004; Mumford and Shah, 1989; Tsai et al., 2001).

Let us consider a parameterized closed surface $C(s) : S = [0, 1]^{L-1} \rightarrow \mathcal{R}^L$ defined in a bounded region $\Omega \in \mathcal{R}^L$. In order to segment the observed image $\mu : \Omega \rightarrow \mathcal{R}$ we propose to minimize the following energy functional:

$$E(C) = a \int_{\omega} (\mu - \epsilon) \partial\Omega + b \int_S |C'| ds, \quad (4)$$

where $\omega \subset \Omega$ and $C = \partial\omega$ is the closed surface. The first term represents the boundary force that attracts the evolving surface toward a predefined segmentation constraint $\epsilon = \text{const}$, while the second term regulates the smoothness of the surface. Here, a and b are positive scalar weights.

The energy functional proposed in Eq. (4) is not easy to solve because of the unknown set of complex surfaces C and unidentified image topologies. The segmentation algorithm developed in this work is based on the implicit representation of deformable models implemented within the framework of level sets. This implicit representation for evolving curves, introduced by Osher and Sethian (1988), allows automatic change of topologies without reparametrization. Using the level set formulation, the boundary surface $C = \partial\omega$ can be modeled as a zero level set of a Lipschitz function ϕ , defined on the entire image domain Ω as (Figure 4):

$$\begin{aligned} C = \partial\omega &= \{x \in \Omega : \phi(x) = 0\}, \\ \text{inside}(C) = \omega &= \{x \in \Omega : \phi(x) > 0\}, \\ \text{outside}(C) = \Omega \setminus \omega &= \{x \in \Omega : \phi(x) < 0\}. \end{aligned}$$

Having the Heaviside function $H(\phi)$ defined on the whole image domain as $\int_{\omega} \partial\Omega = \int_{\Omega} H(\phi) dx$, for $\omega \subset \Omega$, and its corresponding Dirac function $\delta(\phi) = \frac{d}{d\phi} H(\phi)$, we can replace the unknown variable C by the level set function $\phi(x)$

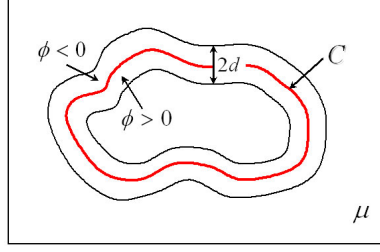


Fig. 4. Narrow band level set approach allows us to compute mapping values only for the points in a narrow band around the zero level set (red line).

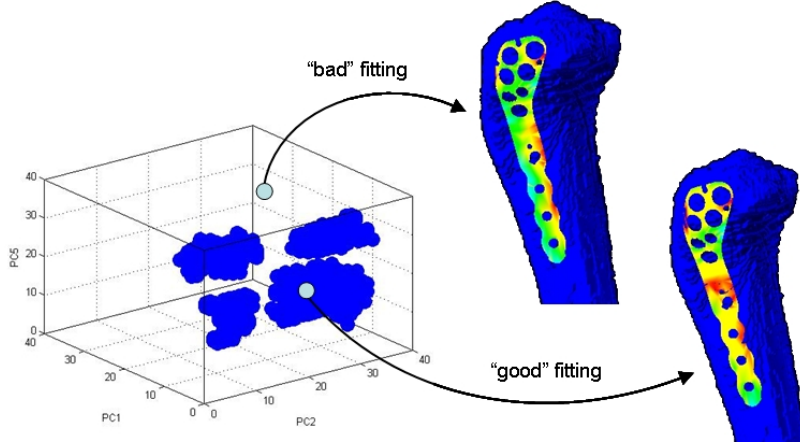


Fig. 5. Level set segmentation of the PCA shape space. Clinical criteria is chosen to be the implant fitting distance to the proximal human tibia. Segmented regions (in blue) satisfy the given segmentation criterion for the 'good' fitting (average fitting distance less than 1mm). Results of the fitting for the instances from 'good' and 'bad' fitting area in the PCA shape space are visualised.

226 as:

$$E(\phi) = a \int_{\Omega} (\mu - \epsilon) H(\phi) dx + b \int_{\Omega} \delta(\phi) |\nabla(\phi)| dx, \quad (5)$$

227 where the surface value $|C(\phi = 0)| = \int_{\Omega} \delta(\phi) |\nabla(\phi)| dx$ is estimated directly
 228 from the level set function (Evans and Gariepy, 1992). By minimizing the
 229 energy functional with respect to ϕ we get a model associated Euler-Lagrange
 230 equation for boundary flow:

$$\frac{\partial \phi}{\partial t} = a (\mu - \epsilon) \delta(\phi) + b \operatorname{div} \left(\frac{\nabla \phi}{|\nabla \phi|} \right) \delta(\phi), \quad (6)$$

231 where t is an artificial time $t \geq 0$ for boundary flow and $\int_{\Omega} |\nabla(\phi)| dx =$
 232 $\operatorname{div} \frac{\nabla(\phi)}{|\nabla(\phi)|}$.

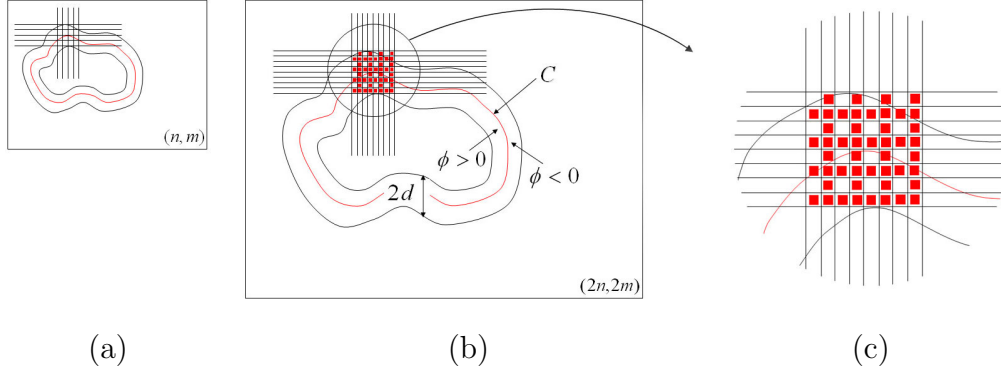


Fig. 6. Hierarchical approach to narrow band zero-level set evolution. (a) Initial low resolution 2D image space map with a stable zero level set in red colour and a narrow band around it. (b) Higher-resolution map with the augmented narrow band and zero level set, adopted from the low-resolution map. (c) The values of white pixels in the grid map come from the low resolution map, while the values of the red pixels that come from the augmented map still need to be calculated.

233 3.3 Level set optimisation in PCA shape space

234 In the framework of our application to the evaluation of anatomical criteria
 235 in PCA shape space, shape space will be the L -dimensional “image” μ to be
 236 segmented, defined in the domain of shape coefficients $\Omega = A$. Thus, level
 237 sets are used to find the region in the shape space defined by the weights
 238 applied to the principal components, in which the criterion is met (Figure 5).
 239 The flexibility of level sets allows to identify disconnected regions of the shape
 240 space. Further, the generality of the method allows to define any criterion,
 241 including complex functions that depend non-linearly on the shapes defined
 242 by the principal components.

243 It must be noted that in this work level sets are not used as a shape repre-
 244 sentation method, as is the case in all previous works that combine level sets
 245 with statistical shape models (employed as prior in the segmentation process).
 246 Rather, we do the analysis in the statistical shape space directly, not in im-
 247 age space, and we deal with the identification of a population, rather than a
 248 particular image.

249 3.4 Hierarchical approach to zero level set evolution

250 In order to decrease the computational complexity of the standard level set
 251 method we extend a narrow band level set approach, which uses only the points
 252 close to the evolving front at every time step (Adalsteinsson and Sethian, 1995)
 253 to hierarchical narrow band level set (HNBLS) approach. First we initialize
 254 our level set function using automatic seed initialisation on a low resolution

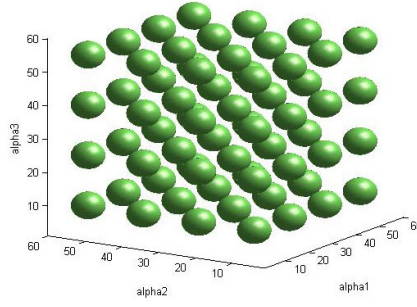


Fig. 7. Seed initialisation of the level set function.

image map. The seed initialisation consists of partitioning the data image u_0 into N windows W_n , $n = 1..N$ (Figure 7). Windows are of predefined size and do not overlap. The size is selected empirically to be $dim(\mu)/15$ in order to detect all the small “irregularities” in the image space and to decrease computational time. Level set function is computed only in these seed points. Then, minimisation of the energy functional (Eq. (5)) is performed to evolve the surface towards the segmented region.

We define a thin band around the zero-level set, that contains the neighboring points with distance to the zero-level less than d_{max} and we update the level set only on these points (Eq.(6)), instead of re-calculating it for each grid point (Figure 6a). As the zero-level set corresponding to the front evolves, we must ensure that it stays within the band. We re-initialise the band after 10 iterations, when the front is close to the edge of the domain, using the current zero-level set as the initial surface. Once the stable boundaries of the low resolution map are reached we increase the resolution of the image space and continue zero-level set surface evolution in the augmented low-resolution narrow band (Figure 6b).

The hierarchical narrow band level set algorithm is as follows (Figure 8):

Step 1. Initialise the zero level set function ϕ^0 , as a corresponding circular signed distance on each window W_n . Construct a thin band around zero-level set $\beta^0 = N(\phi^0)$.

Step 2. Update ϕ^{k+1} for all pixels on β^k (Eq.(6)). If $k(mod10) = 0$ then go to Step 4, else if k is equal to a maximum number of iterations, then stop.

Step 3. Update narrow band β^k and assign values to new pixels on narrow band. Outside the domain the value is defined as: $\phi^{k+1} = +d_{max}$ if the point is inside of the curve and $\phi^{k+1} = -d_{max}$ if the point is outside of the curve. Go back to Step 2.

Step 4. Increase the resolution of the image space and compute the values of the missing pixels in the augmented low-resolution narrow band. Go back to Step 2 (Figure 6).

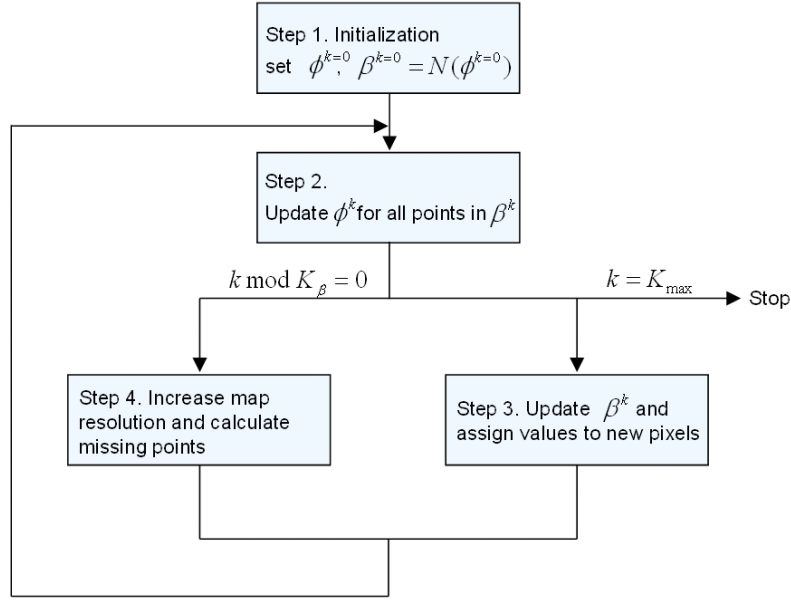


Fig. 8. Hierarchical level set segmentation algorithm.

4 Optimisation of orthopaedic implant designs

4.1 Clinical context

Since the late 1950s, open reduction and internal fracture fixation has been used to restore bone anatomy and enable early mobilization. Internal fixation alters the biology of fracture healing and reduces strain at the fracture site. Plate contouring is an important step in osteosynthesis. Plates are pre-contoured before or during a surgery to match either patient-specific or an average bone anatomy. The safety and ease of this procedure depends on certain material properties of the plate, such as the yield point and fatigue endurance (Frankel and Burstein, 1970). In addition to this, contouring is affected by the complexity of the bone shape to which the plate has to fit.

Nowadays, with an annual incidence of over a half million fractures of the tibia and fibula in the US (Russell and Levine, 1996), manufactures are moving from costly patient-specific implant design to the average implant shape that can fit to a given population.

Currently in orthopaedic research, the evaluation of implants for fracture fixation is done by manual fitting and fixation procedures, applied on a small set of cadaver bones in a trial-and-error process to determine the optimal implant shape and position (Figure 9). Goyal et al. (2007) investigated the accuracy of the periarticular tibial plate fit using 101 cadaver specimens of human tibia, on whom the implants were manually fixed by visually finding the best implant



Fig. 9. Internal fixation of the proximal tibia implant.

position. More recently, a noninvasive semi-automatic method for quantifying
implant fitting was developed (Schmutz et al., 2008). In this study the surface
of the plate was fitted to 21 computer tomography (CT) based 3D models of
human tibia. Although the recommendations for implant modifications were
discussed, there are no conclusive results on how these modifications would
improve fitting.

4.2 Automatic implant fitting algorithm

A modified Iterative Closest Point (ICP) technique (Besl and McKay, 1992),
developed in our group (Reyes et al., 2008), was used for the specific task of
bone implant fitting. The method initialises the position of the implant close
to the bone surface and optimises its position as to fit the bone as closely as
possible, subject to specified positioning constraints. Based on this result, it
computes the distance map from each point in the implant to the closest point
in the bone surface.

In this work, the method is refined by a modified collision constraint to ensure
that no points in the implant mesh model fall inside the bone model. Colli-
sion detection is performed by tracking the change of direction between the
vector pointing from the inspected point to its closest point to the mesh and
its normal vector. In addition, fitting guidelines provided by the implant man-
ufacturer were included as fitting constraints, this in order to find plausible
implant fittings. These further specific constraints favor fittings of the implant
that are collinear with the bone main axis, and do not take place above the
bone plateau (Figure 10).

The constrained ICP algorithm is based on the optimization of the following
functional:

$$\operatorname{argmin}_i \sum_i W_i \|e_i\|, \quad (7)$$

where W_i and e_i are the corresponding weight and distance error for point
 i in the implant mesh model, respectively. The weights W_i are computed as

333 a linear combination of constraint-specific weights for collision W_i^C , implant-
 334 bone collinearity W_i^{\parallel} , and tibia plateau W_i^p :

$$W_i = W_i^C + W_i^{\parallel} + W_i^p. \quad (8)$$

335 The collision weight W_i^C is computed as follows:

$$W_i^C = \begin{cases} 1 & p_i \notin V_{in} \\ k_i^c \|e_i\| & p_i \in V_{in} \end{cases}, \quad (9)$$

336 where V_{in} is the 3D space inside the bone model. To detect if a point p_i is
 337 inside or outside the bone model, the sign of the dot product between the
 338 normal vector on the bone surface closest to p_i and the vector formed by p_i
 339 and its closest point on the bone surface is computed.

340 In order to avoid biases due to the number of points inside and outside the
 341 volume, the variable k_i^c in Eq. (9) is proposed by the following inequality:

$$k_i^c \geq (N_{tot} - N_{in}) / \sum_{i \in V_{in}} \|e_i\|, \quad (10)$$

342 with N_{tot} the number of points of the implant mesh, and N_{in} the number of
 343 points falling inside the bone model. We have found that adjusting the weight
 344 k_i^C we avoid biases due to the number of points inside and outside as the
 345 iterations proceed.

346 Similarly as for the collision constraint, weights W_i^{\parallel} , and W_i^p are computed as
 347 follows:

$$W_i^{\parallel} = \begin{cases} 1 & \alpha \leq \alpha_{th} \\ k^{\parallel} \|\alpha_{th} - \alpha\| & \alpha > \alpha_{th} \end{cases}, \quad (11)$$

348

$$W_i^p = \begin{cases} 1 & p_i \in \Gamma \\ k_i^p \|p_i - \Upsilon\| & p_i \notin \Gamma \end{cases}, \quad (12)$$

349 where α is the angle between the implant main axis and the bone main axis,
 350 α_{th} is a threshold angle chosen by the user, k^{\parallel} is a scalar chosen empirically
 351 and used to weigh the global effect of the parallelism constraint, Υ is the z-
 352 coordinate of the plateau region interface, and Γ is the 3D space above the
 353 bone plateau (Figure 10).

354 For the computation of α the main axis of the implant model and the bone
 355 are required. This is performed through a Oriented-Bounding-Box (OBB) de-
 356 composition of both shapes (Figure 11b). Furthermore, for the implant model,
 357 only the lower region is used in order to improve the alignment between the
 358 bone shaft and the implant.

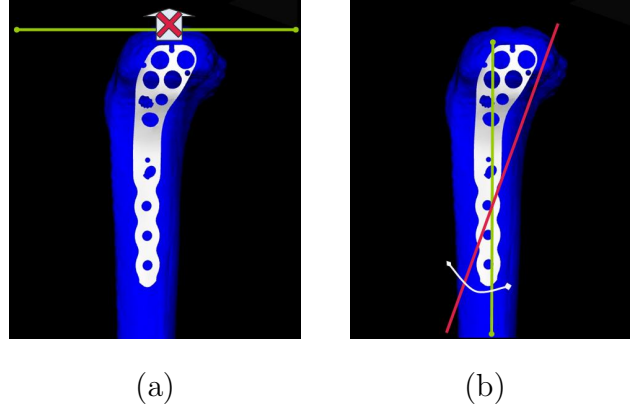


Fig. 10. The constraints proposed by the implant manufacturer: (a) plateau constraint and (b) parallelism constraint.

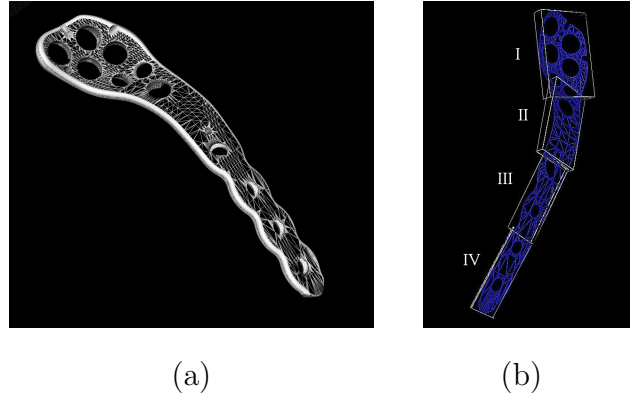


Fig. 11. (a) The original implant model and the extracted inner surface. (b) The Oriented-Bounding-Boxes of the implant.

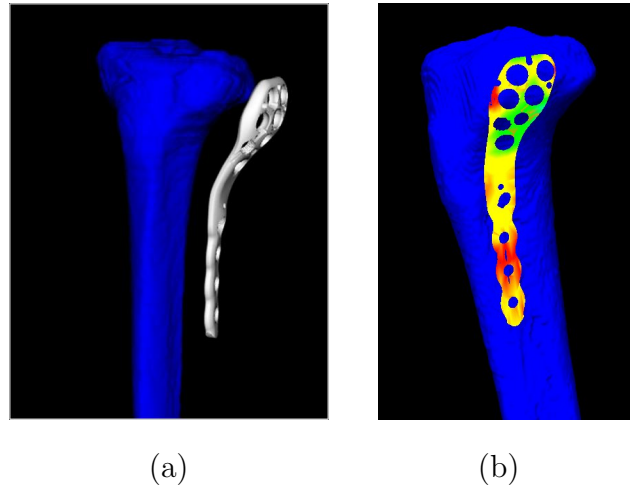


Fig. 12. (a) The initialisation of the implant fitting. (b) The final result of the implant fitting shows the distance map of fitting error, where the red colour represents the perfect fitting of the implant to the bone and the green colour represents the distance of 3mm to the bone surface.

Figure 12 shows the initialisation step of the automatized implant fitting procedure and the final result of the fitting where the colour map of the implant represents the distance map of the fitting error.

4.3 Population-based evaluation of implant fitting

We apply our method to evaluate the performance of orthopaedic implants, used for internal fracture fixation of the proximal tibia, within the context of the PCA space level set evaluation framework described in Section 3, to optimise the implant shape as to fit a majority of the target population. Figure 13 illustrates the complete procedure.

We present results obtained from a training set of tibia surface models extracted from CT data. The training set consists of 92 left human tibiae from which Asian, Caucasian, male and female are equally present. Statistical shape modeling was then performed, as explained in Section 2. We retain the first five principal components, which account for 92% of shape variability in the population. Using more than five modes to explain the statistical model would give us more subtle changes which, however, do not bring modifications in the area of implant placement (Figure 14). We define the mapping transformation \mathcal{M} as the mean error distance from 844 points sampled on the implant surface to their corresponding best fitted points on the bone surface. The PCA shape space is then built by sampling the space of shape coefficients, generating the corresponding shape, and then computing the mapping \mathcal{M} to obtain the measure of interest. We use the range $-3 \leq \alpha_i \leq 3$ for every shape coefficient. This accounts for 99.7% of the shape variability encompassed in each principal component.

We start with a low resolution sampling of the PCA space, namely a sampling step of $\Delta\alpha_i = 0.1$ for each principal component (which would result in a map of 60x60 instances if two principal components were retained). We initialise the zero level set by applying seed initialisation on the PCA shape space, and then proceed with the hierarchical narrow-band zero level set evolution, as explained in Section 3.4. We do not need to explicitly generate all instances and compute mean error fitting for every point in the shape space, but only in the narrow band around the evolving zero level set. We continue with a hierarchical narrow band approach by reducing successively the sampling step to $\Delta\alpha_i = 0.05$ and $\Delta\alpha_i = 0.025$, respectively. As sampling resolution increases, the narrow band level set approach becomes mandatory to decrease high computation times and to reduce the search space of shape parameters.

For the given implant fitting problem, which includes space optimisation, instance creation and fitting without manual initialisation, we need less than

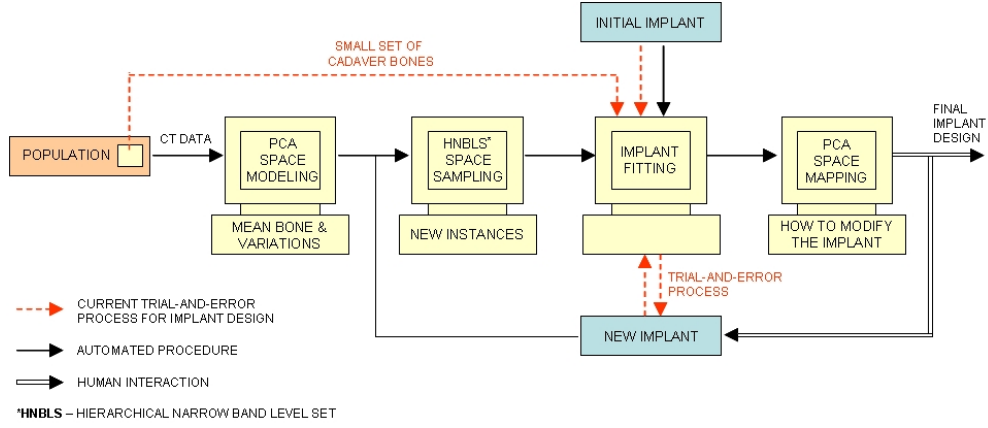


Fig. 13. The complete procedure of the implant design process. First a statistical model of a given population is computed and new instances are created (PCA shape space modeling and HNBL'S 'sampling'). The implant is automatically fitted to these virtual bones and a mean error of the fitting is computed (PCA shape space 'mapping'). Using hierarchical narrow band level set segmentation 'good' fitted bones are selected. From observing the selected instances and the fitting results on them we could propose modifications to the implant shape. Finally, we repeat the process of automatized fitting for new implant to verify its performance.

1 minute per bone (Dual CPU @2.2 GHz, RAM 2GB). In combination with hierarchical narrow band and a given segmentation criterion the fitting process was performed on 1'504, 1'168 and 4'904 instances, respectively for the 3 resolution levels mentioned above. This results in reducing the computation to only 13.5% of the whole shape space (i.e. 57'600 instances), which drastically reduces the computation time.

The segmented areas in Figure 15a represent the range of parametric values that generate tibia shapes satisfying the segmentation criterion that was provided as a requirement from the implant designer, i.e. mean fitting error of less than 1mm. The 2D shape space map is built using 2 principal components, u_1 and u_2 , in order to illustrate the strong effect of the first principal component for the implant shape design. Figure 15b shows an example of a construction of a 3D PCA shape space (i.e. using 3 principal components to generate the shape instances) and the result of the level set optimisation for the fitting error less then 1mm. It can be visualised that the first and fifth PCs have higher influence on the implant shape design, whereas the second PC does not interfere much as it covers the whole space $-3\sqrt{\lambda_2}, +3\sqrt{\lambda_2}$. We decided to exclude principal components u_3 and u_4 since their variations do not affect the bone in the area of the implant placing (Figure 14).

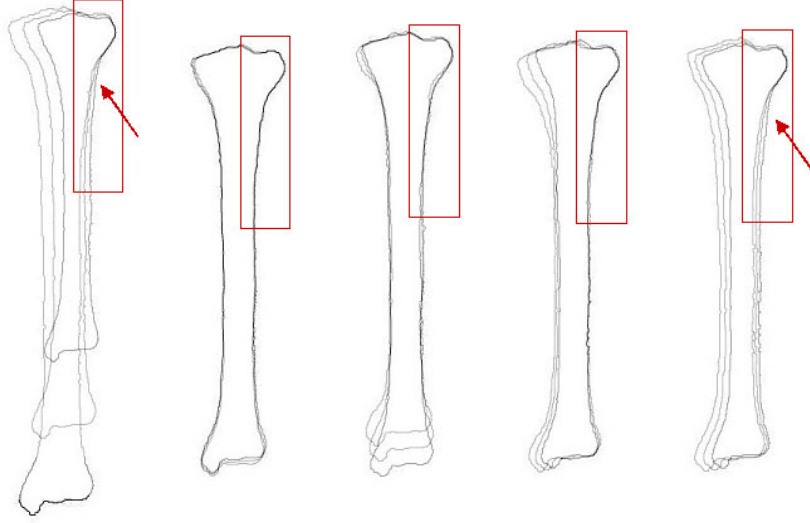


Fig. 14. The first five modes of variation for the left human tibia (anterior view) are visualised. For each principal component, we show $\bar{m} - 3\sqrt{\lambda_i u_i}$, \bar{m} , and $\bar{m} + 3\sqrt{\lambda_i u_i}$, where \bar{m} represents the mean bone. The arrows point to the area of implant placement, which is most affected by the first and fifth principal component. The first five modes account for 71, 11, 6, 3 and 1% of shape variability in the population, respectively.

4.4 Implant design modifications and analysis

Implant design modifications followed analysis of the segmented spectrum of shapes. It can be seen in Figure 15a that the result of the fitting depends mostly on the first principal component, as the segmented area falls in the negative values of u_1 . Since the negative values of the first principal component favor 'good' fitting, this leads to the conclusion that the implant works better for longer bones. Our aim is to optimise the fitting as to cover the whole shape space, i.e. the majority of the population. Having the measure of variation between positive and negative values for the first principal component (Figure 14), it can be concluded that changes of the length of the tibia affect the result of the fitting, since these changes affect as well changes of the oblique line of the tibia and a slight torsion of the lateral surface of the tibia. In other words, the analysis allows us to conclude that the angles and curvatures in the first and second OBB of the implant geometry (Figure 11b) as well as the curvature of the third and fourth OBB of the implant are responsible for the fitting.

In agreement with the previous conclusions we proceed with the optimisation of implant shape design by applying the following modifications. First, we decrease the angles and flatten the curvatures in the first and second bounding box of the implant (Figure 16a), to follow the oblique line of the mean tibia

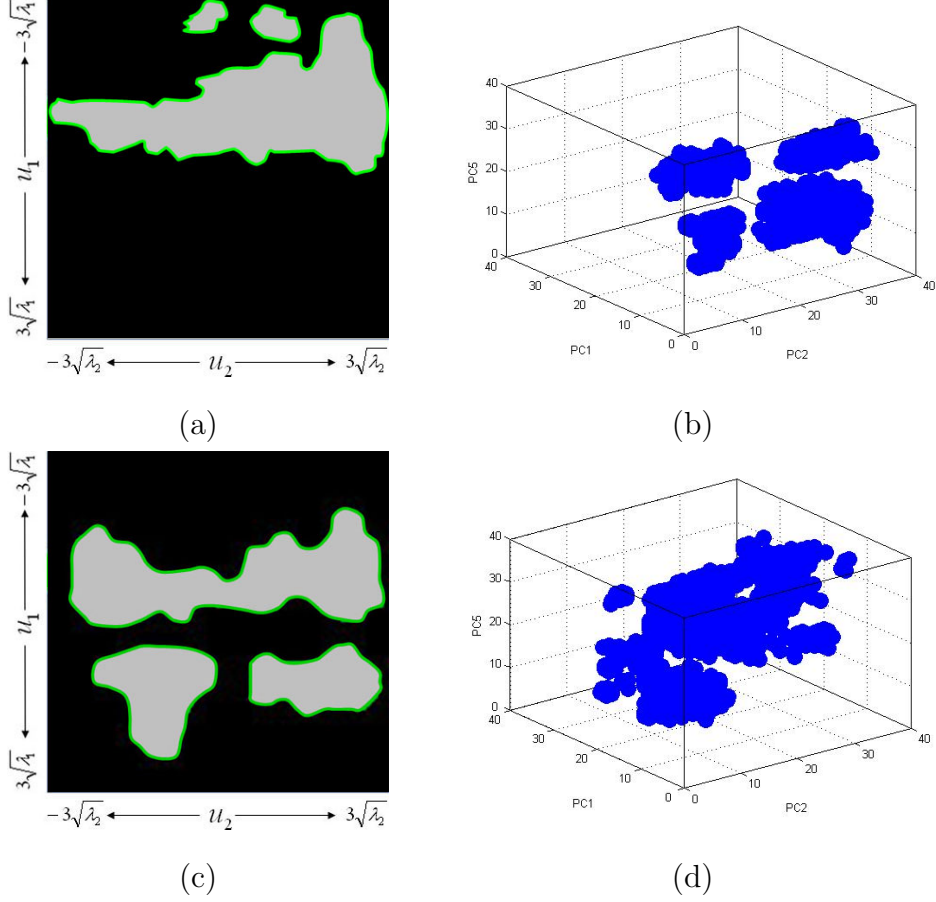


Fig. 15. (a) Automatic hierarchical 2D level set segmentation gives the spectrum of shapes that have fitting error less than 1mm for the implant given by the manufacturer. (b) 3D level set segmentation gives the spectrum of shapes that have the fitting error less than 1mm for the implant given by the manufacturer. (c) Spectrum of shapes that have fitting error less than 1mm for the modified implant design. (d) 3D level set segmentation for the modified implant design.

bone (Figure 14). In addition, we follow the distance dimensions between bone head and implant from the implant fitting distance map (Figure 12b). We apply further modifications to the implant shape by increasing the torsion of the distal part of the plate. We rotate the third and fourth bounding box along the center of the plate to bring the left anterior edge of the implant closer to the lateral surface of tibia (Figure 16b).

To evaluate the new design we perform a re-fitting in the PCA shape space using the modified implant shape. The results of the segmented space are shown in Figures 15c and 15d. It can be seen that the modified implant expands the space of segmented bones by covering different shape variability and therefore fits better to the majority of the population. With the new implant design we found that there is an increase of 40% on the number of instances that satisfy the given fitting criterion.

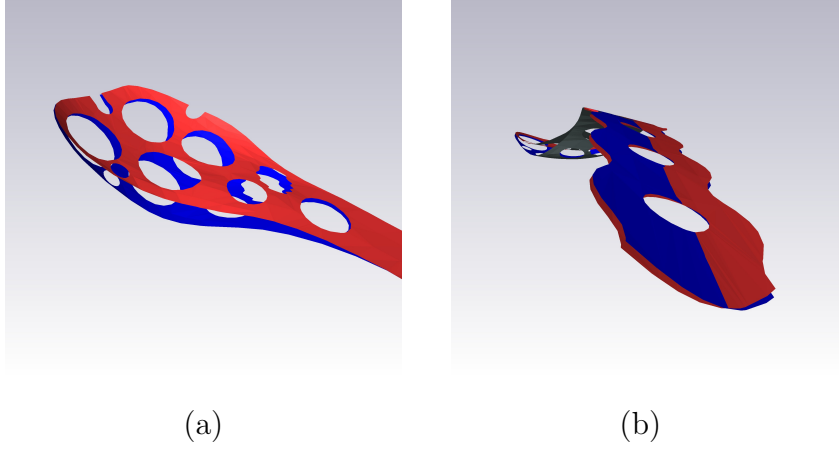


Fig. 16. New implant design (in red). (a) Curvatures in the first and second bounding box of implant are flattened. (b) Implant surface in the third and fourth Oriented-Bounding-Box is twisted inside.

5 Conclusions

In this paper we have presented a methodology for the evaluation of a functional criterion (that could represent an anatomical/physiological measure) across a target population. Our framework is based on building a statistical model via PCA and finding the region of the parametric space defined by the principal component weights that matches the criterion. The mechanism to search for this partition is based on a level set evolution in parametric space, optimised via a multi-level narrow-band approach for computational efficiency. To our knowledge, this is the first work that tackles the issue of finding a partition of PCA space based on a criterion, and the first time that level sets are used within this context. Existing previous works combining PCA and level sets used the later as a shape representation, and evolve the level set in image space. This is fundamentally different to our work.

Current evaluation and optimisation of orthopaedic implants is done by manual fitting and fixation procedures, applied on a small set of cadaver bones in a trial-and-error process. The method that we propose allows to virtually test the implants on a representative set of bones generated by sampling the statistical model. Using level sets a spectrum of shapes is segmented in the PCA shape space, based on a given fitting criterion. By correlating the principal components of the selected instances to the given implant geometry the modifications to the implant design/geometry can be assessed directly from the segmented map. The proposed method highlights which patterns of bone variability are more important for implant fitting, allowing and easing implant design improvements, as to fit a maximum of the target population. A hierarchical narrow band approach is used to avoid exhaustive search of the instances in the high resolution space, and to search for the instances only in

475 the neighborhood of the zero level set and not in the whole shape space.

476 To our knowledge this is the first research into the problem of estimating
477 how a given implant fits to the wide population and how the morphological
478 features in implant design can be improved. The practical use of the proposed
479 concept are of great importance for the implant manufacturer, due to the huge
480 potential benefits in terms of patient satisfaction and financial gains in this
481 high-volume market. Further validation of the method is ongoing work.

482 Future work will include automatic correlation of the principal components
483 to the given implant geometry, so that the modifications to the implant de-
484 sign/geometry could be assessed directly from the segmented map and au-
485 tomatically proposed. A parametric model for the implant design could be
486 established, including design parameters such as diameters, lengths, positions
487 of the holes, etc. Such parameters could be automatically optimised by max-
488 imising the fitted volume in the PCA space.

489 Furthermore, we intend to include the application of the proposed method to
490 bone implant fitting assessment taking into account shape and biomechanical
491 properties. A combined shape and intensity statistical bone model will be
492 built, and the intensity values, which are linked to bone density, will be used
493 to do a finite element analysis of the performance of the implant (Belenquer
494 et al., 2006), which will be used as the criterion to be evaluated in the level
495 set evolution.

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Figure1

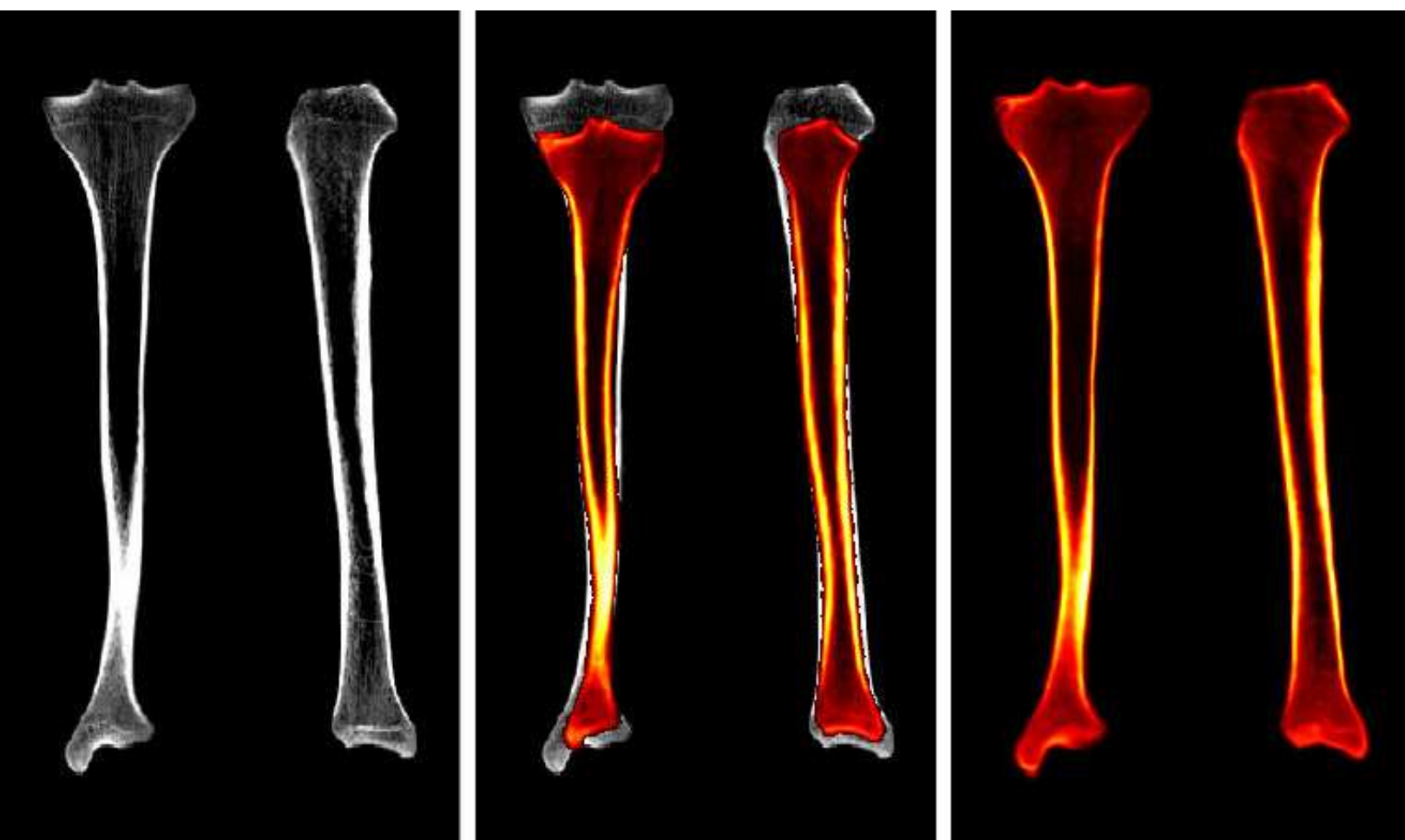


Figure2

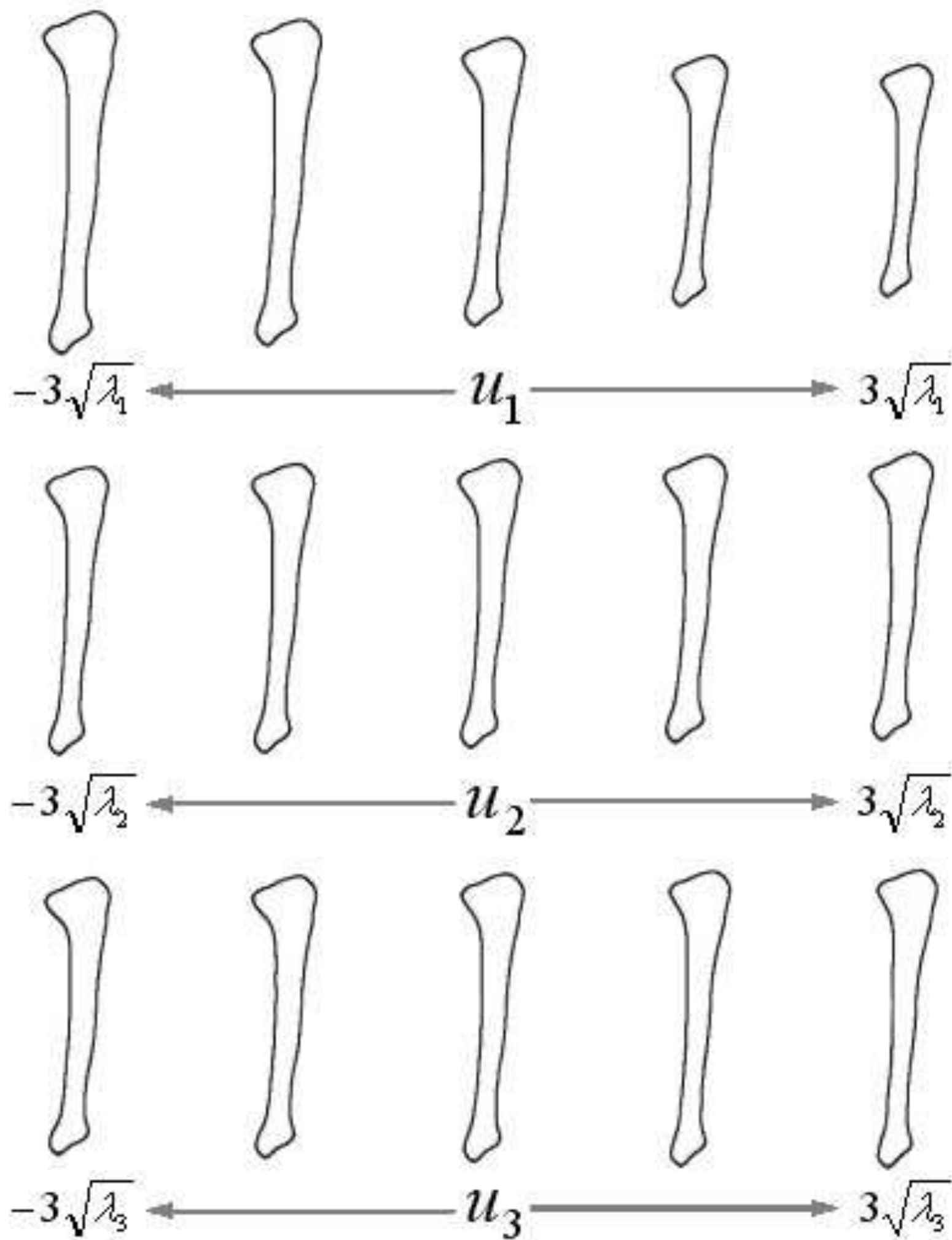


Figure3

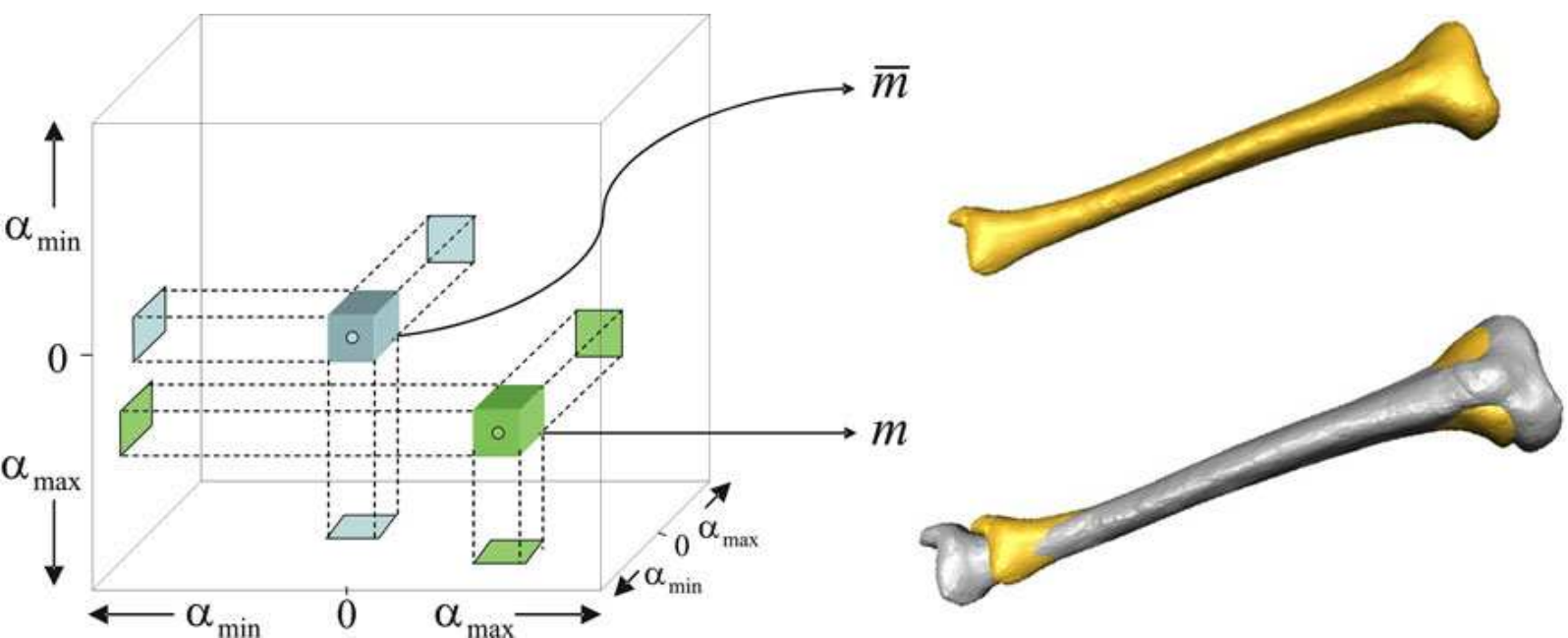


Figure4

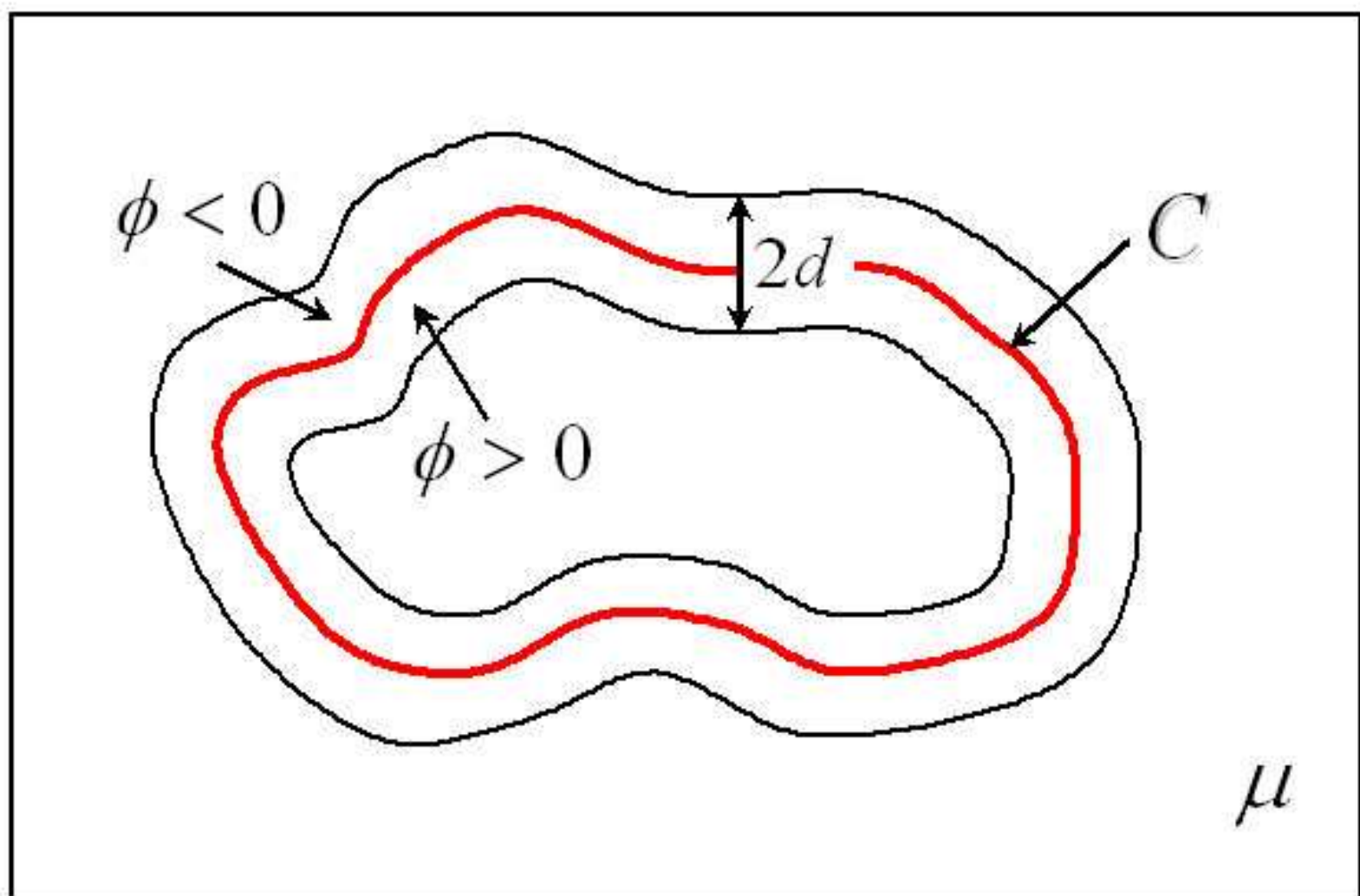


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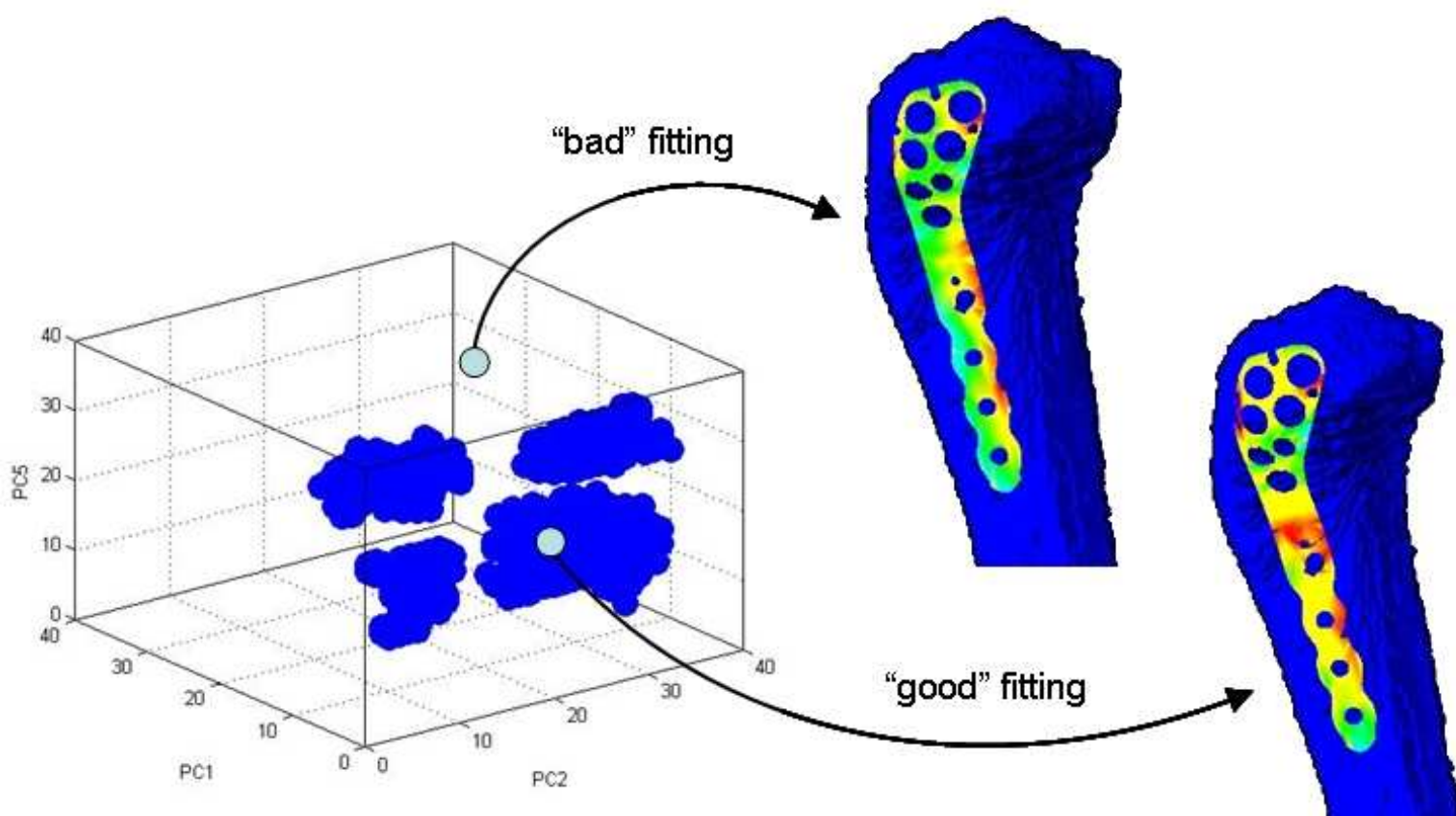
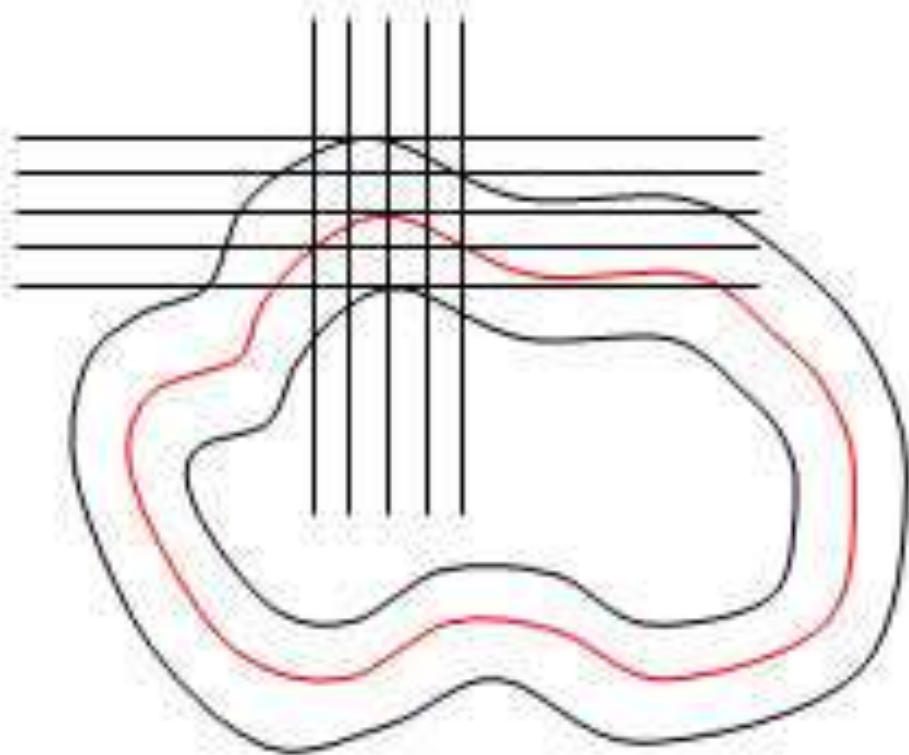


Figure6a



(n, m)

Figure6b

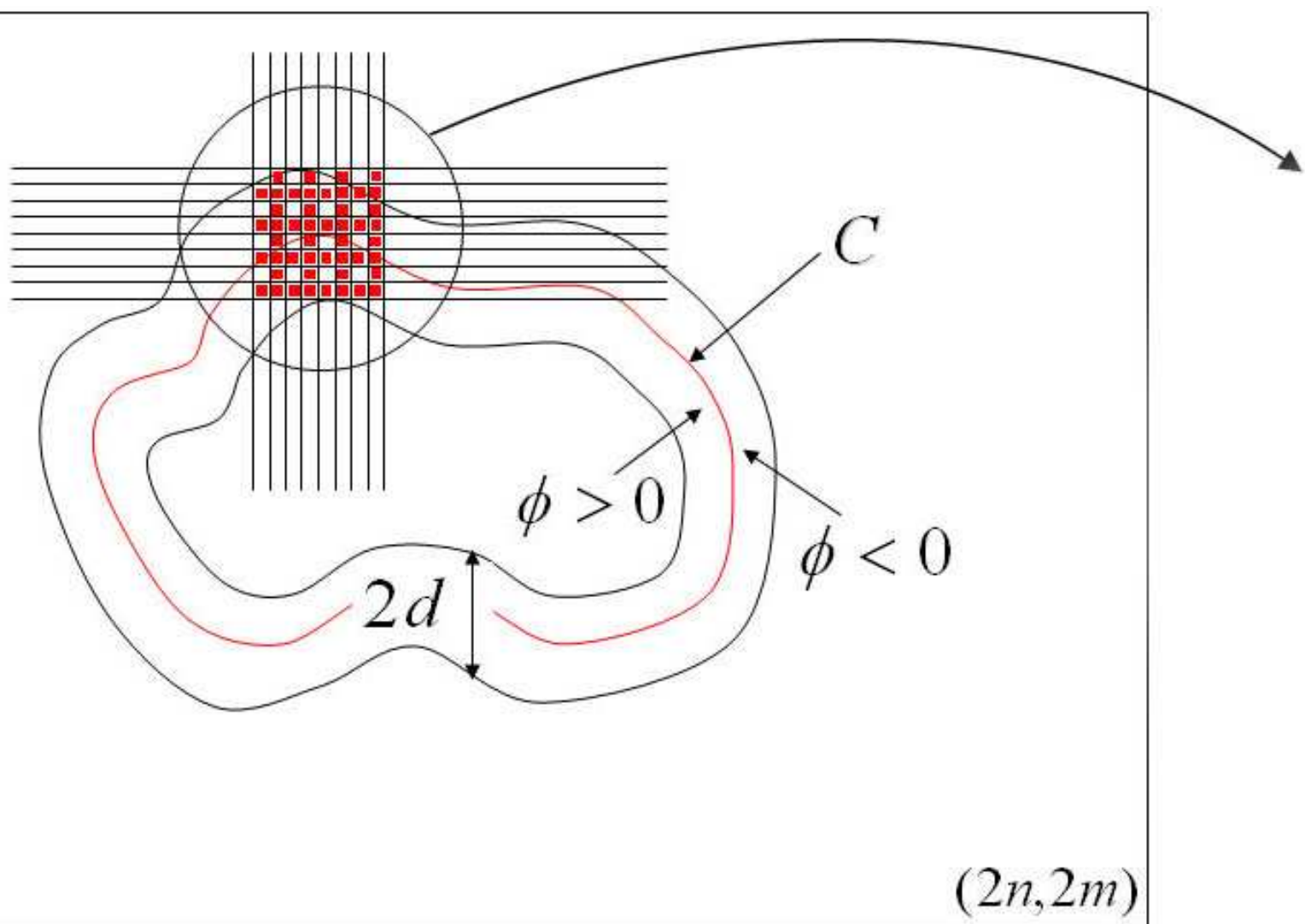


Figure6c

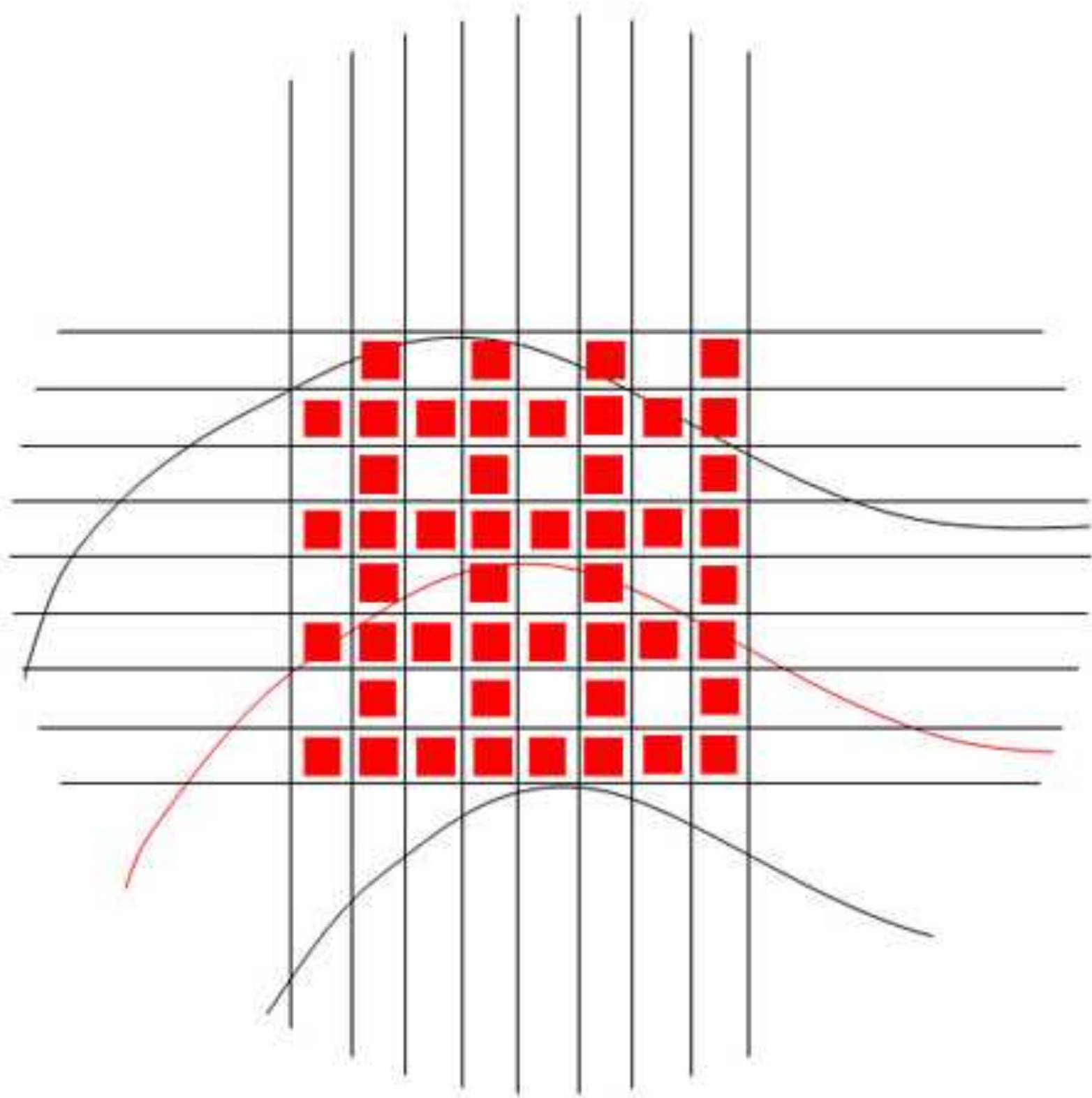


Figure7

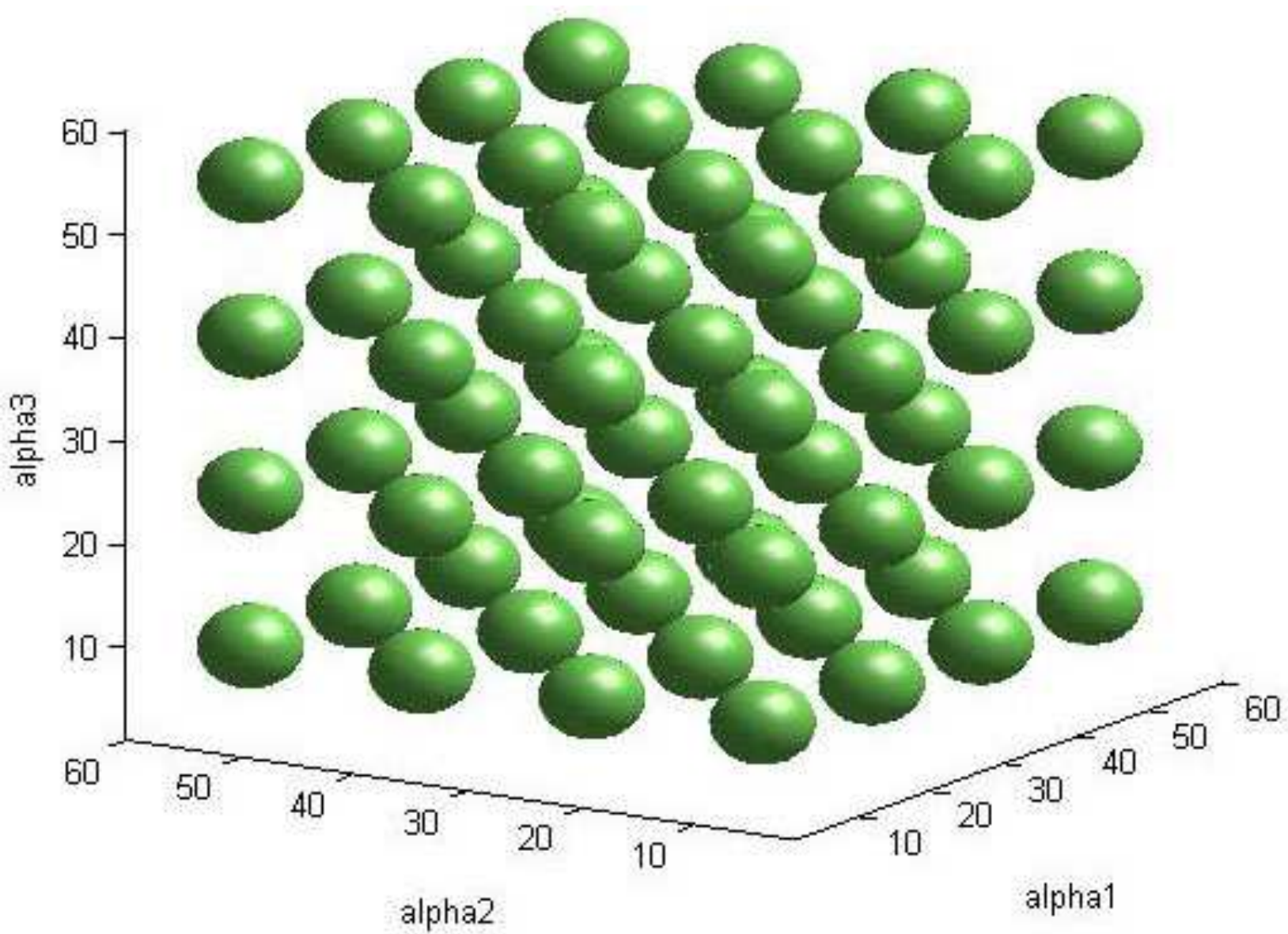


Figure8

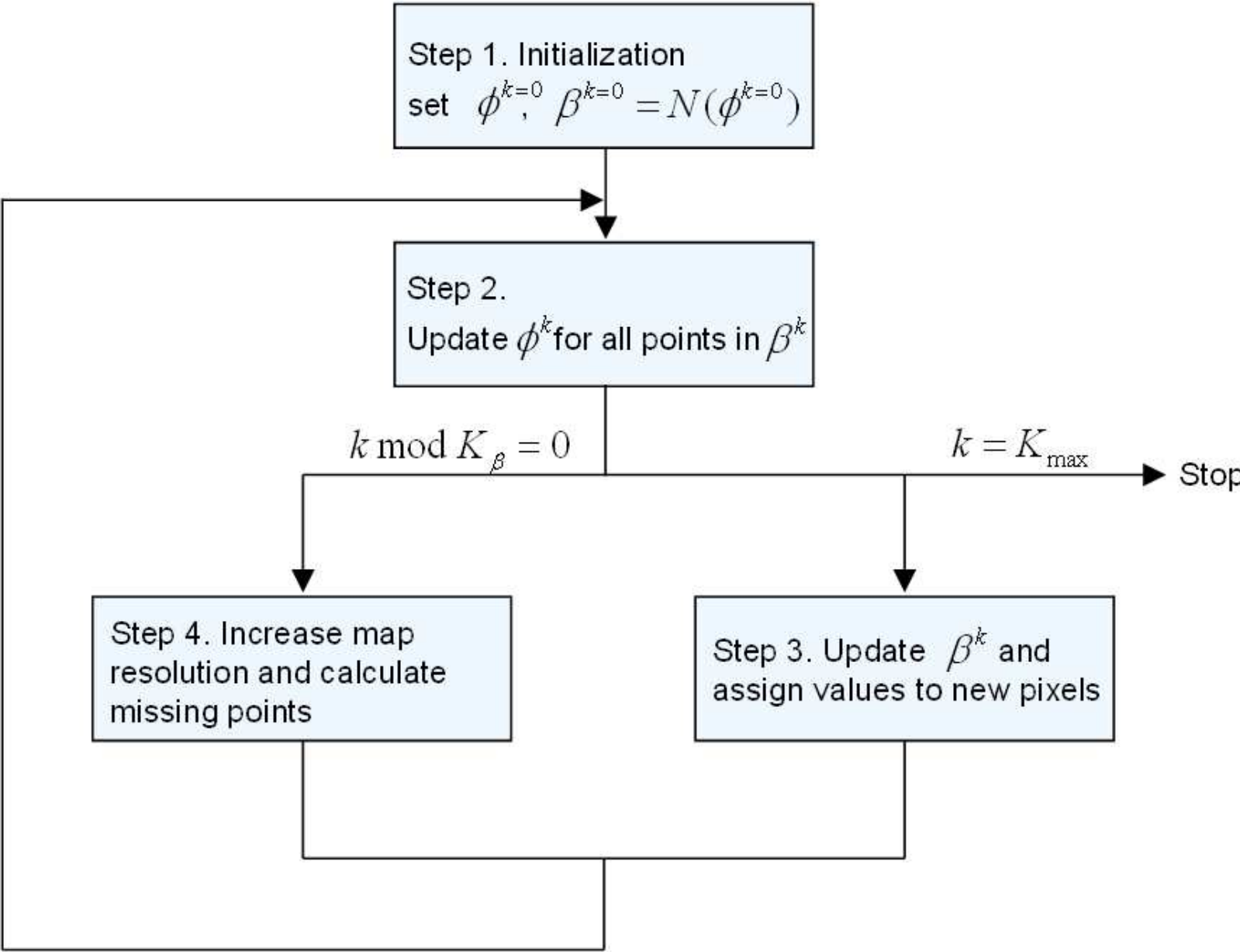


Figure9

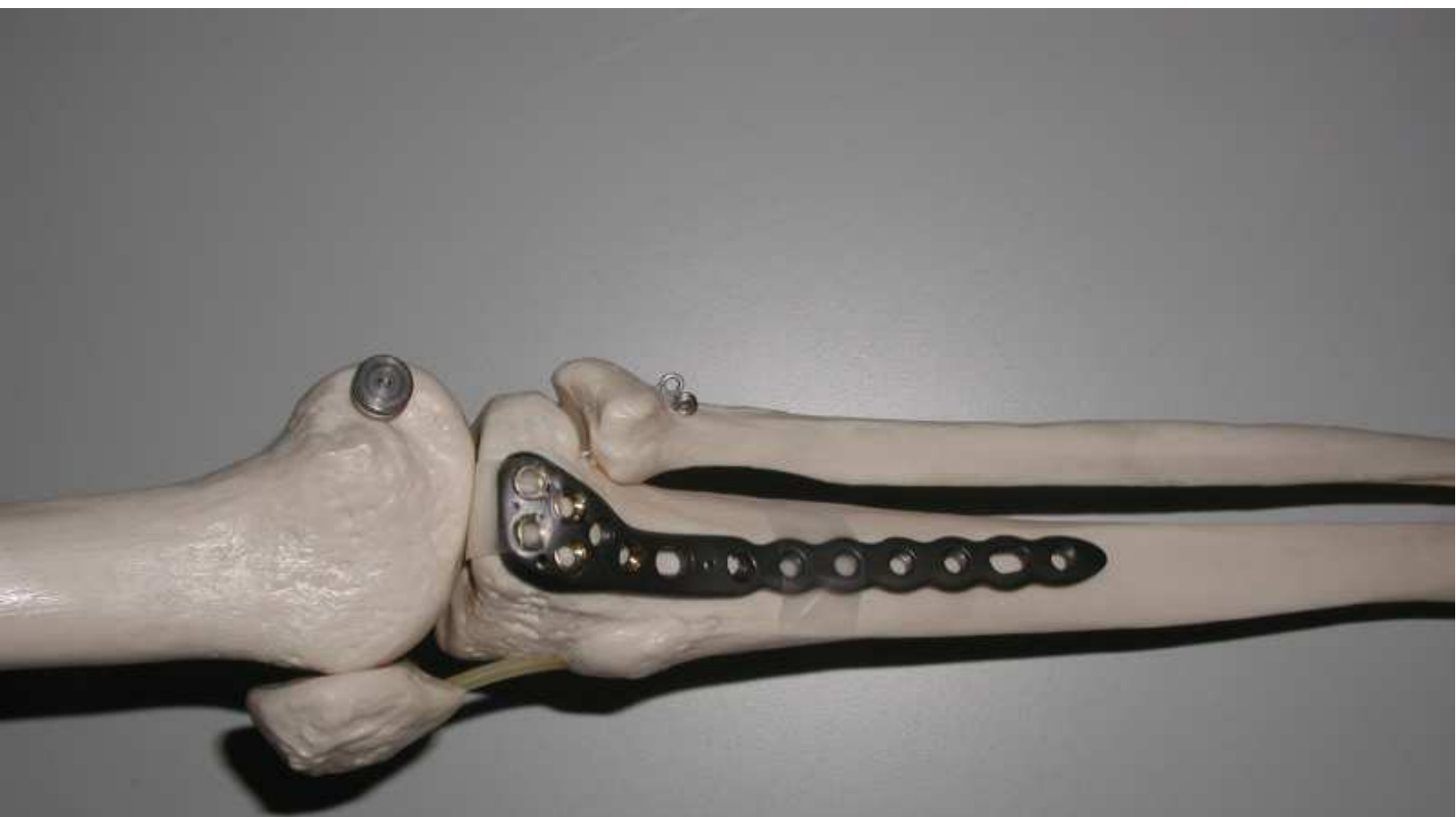


Figure10a

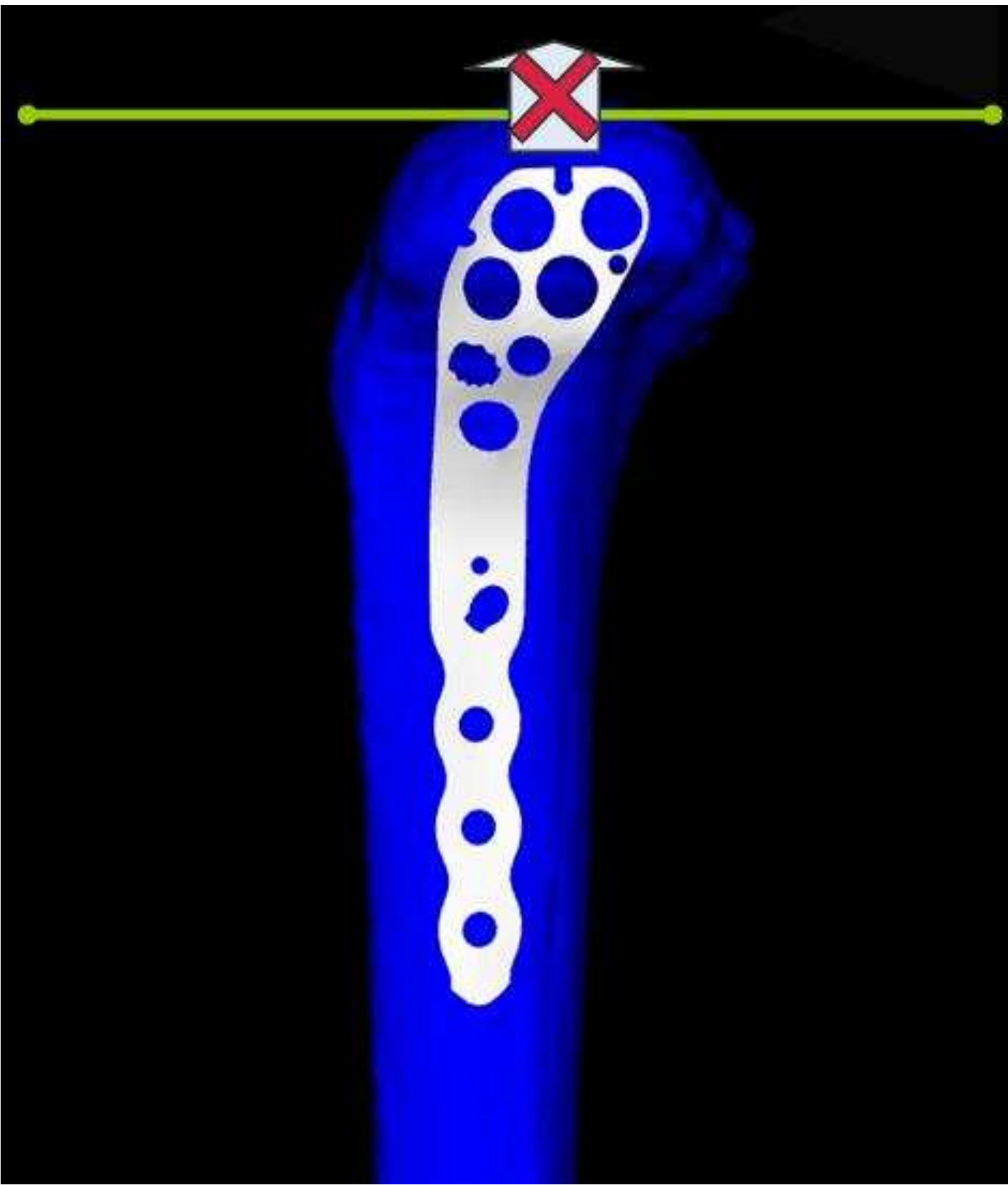


Figure10b

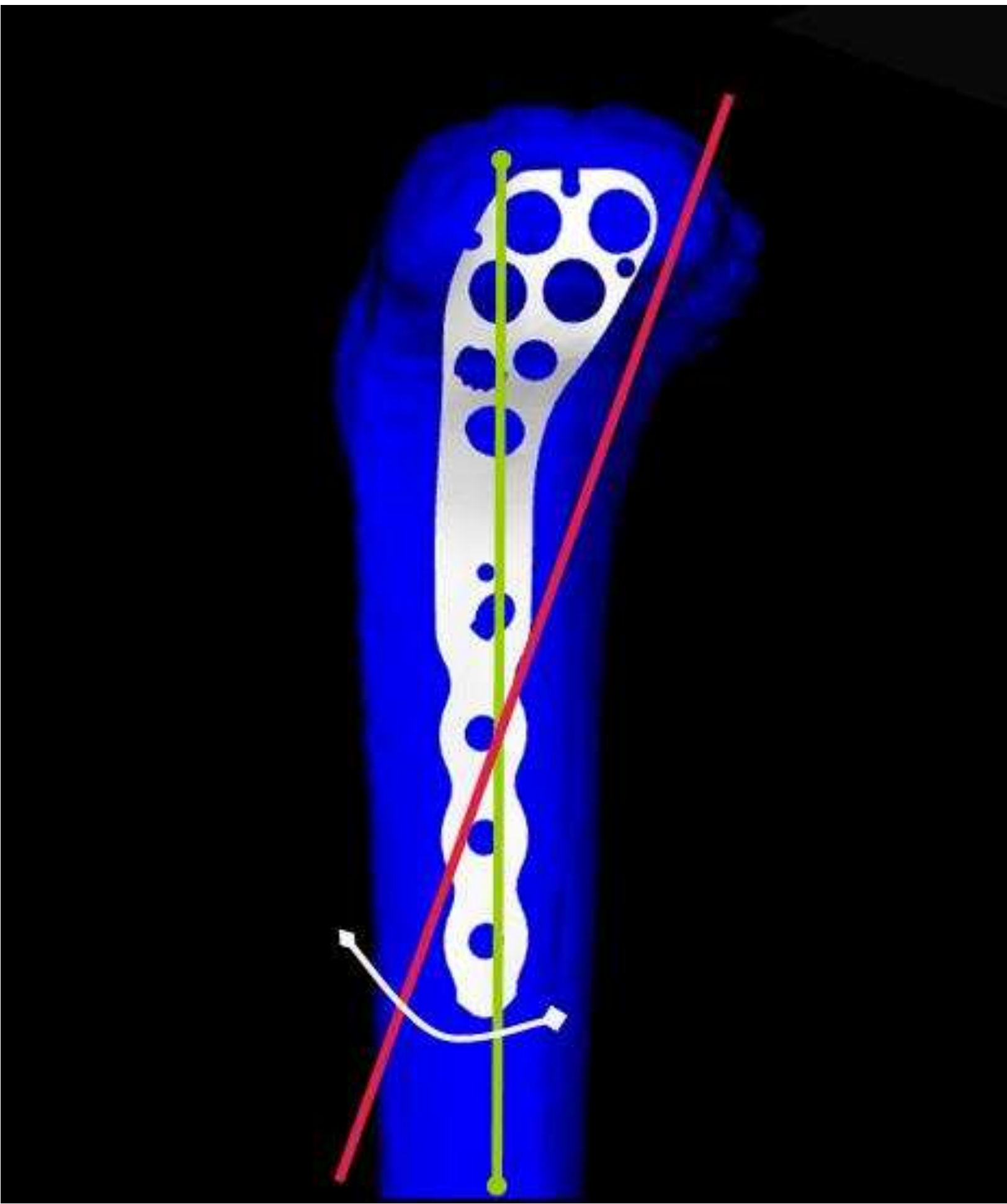
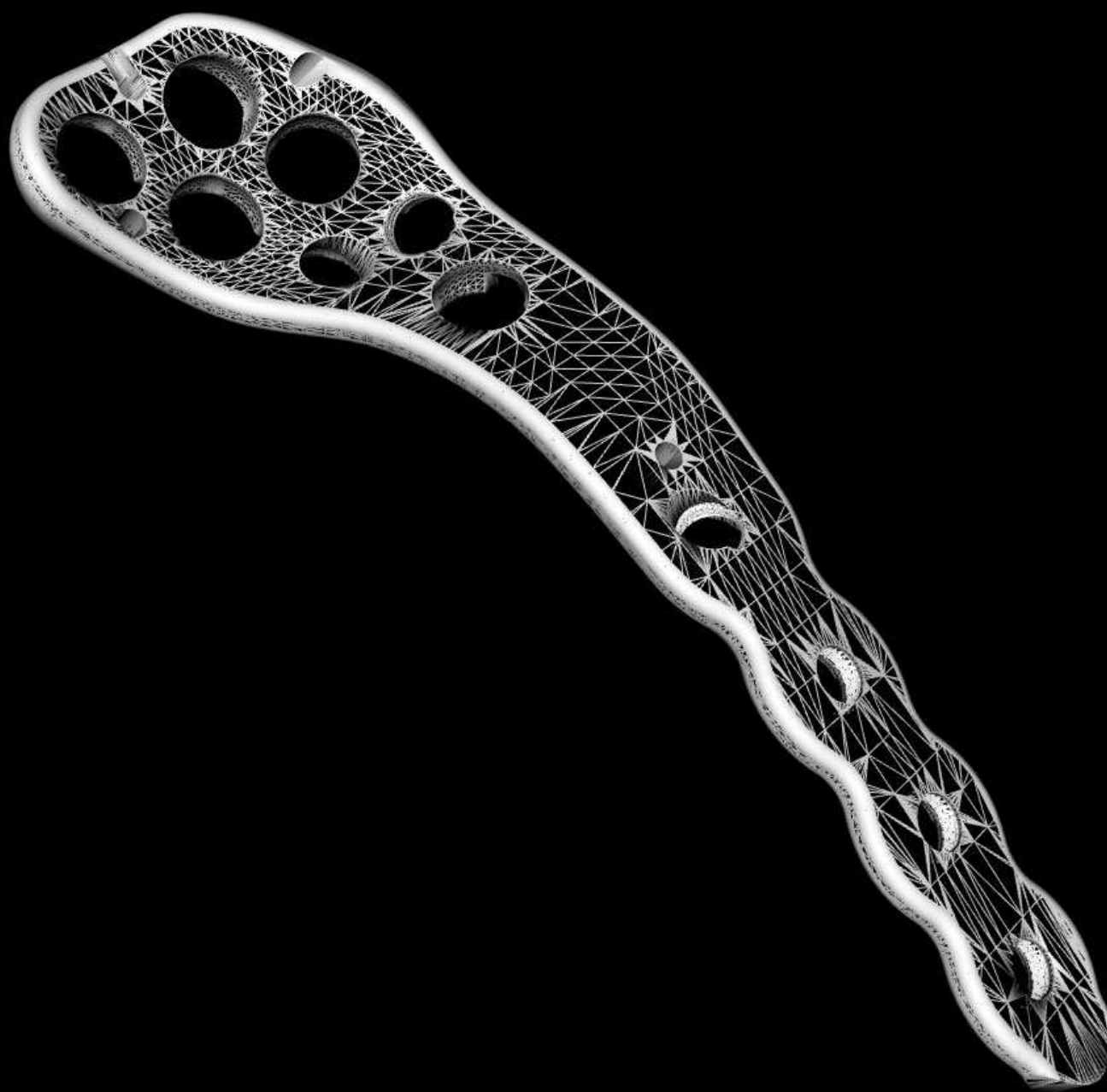
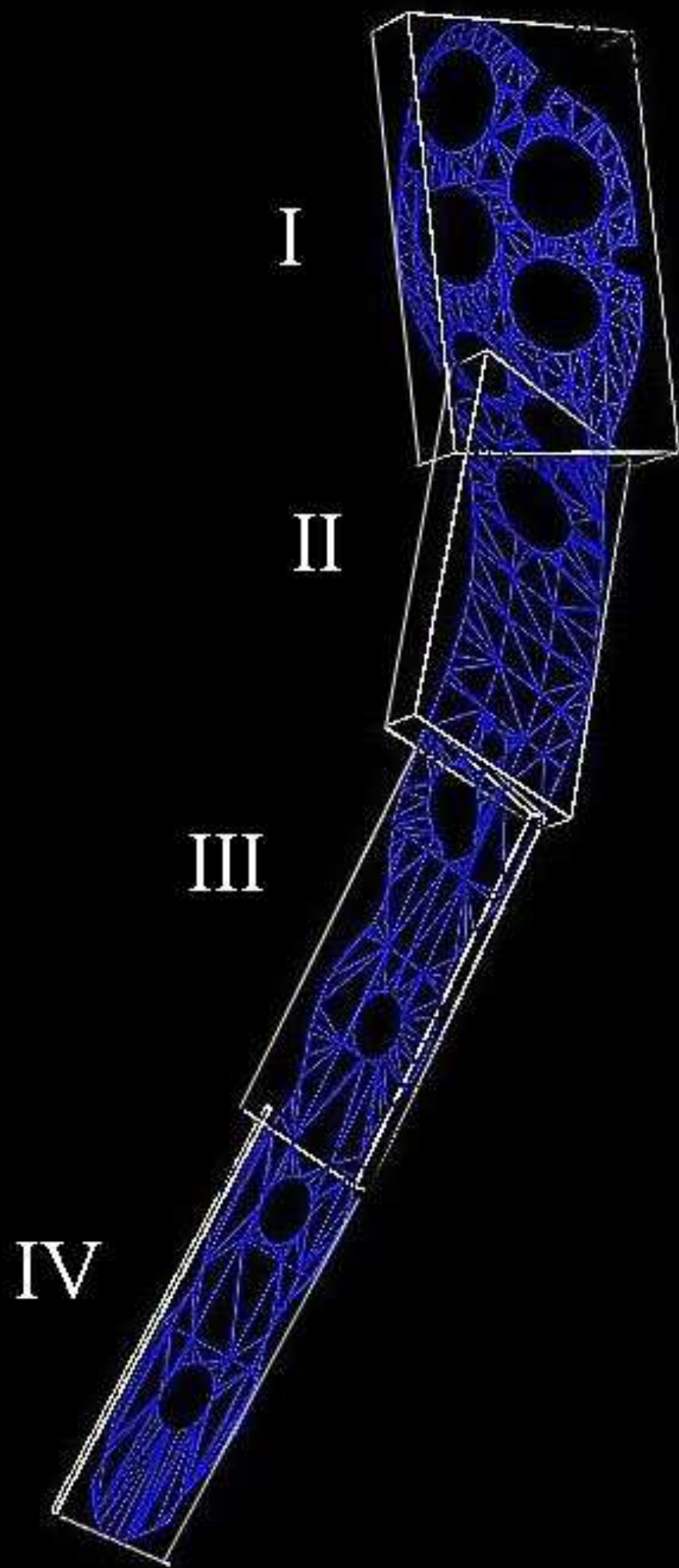


Figure11a







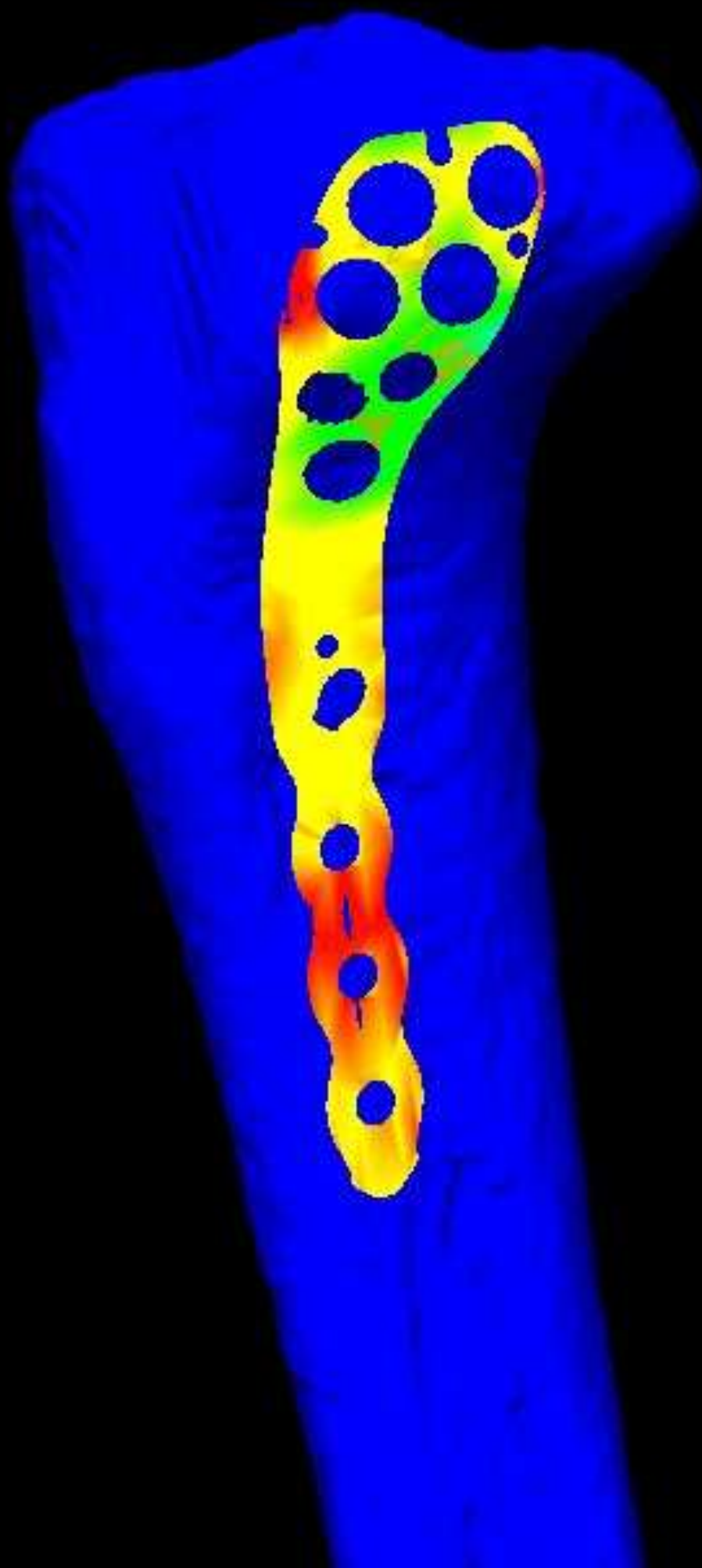
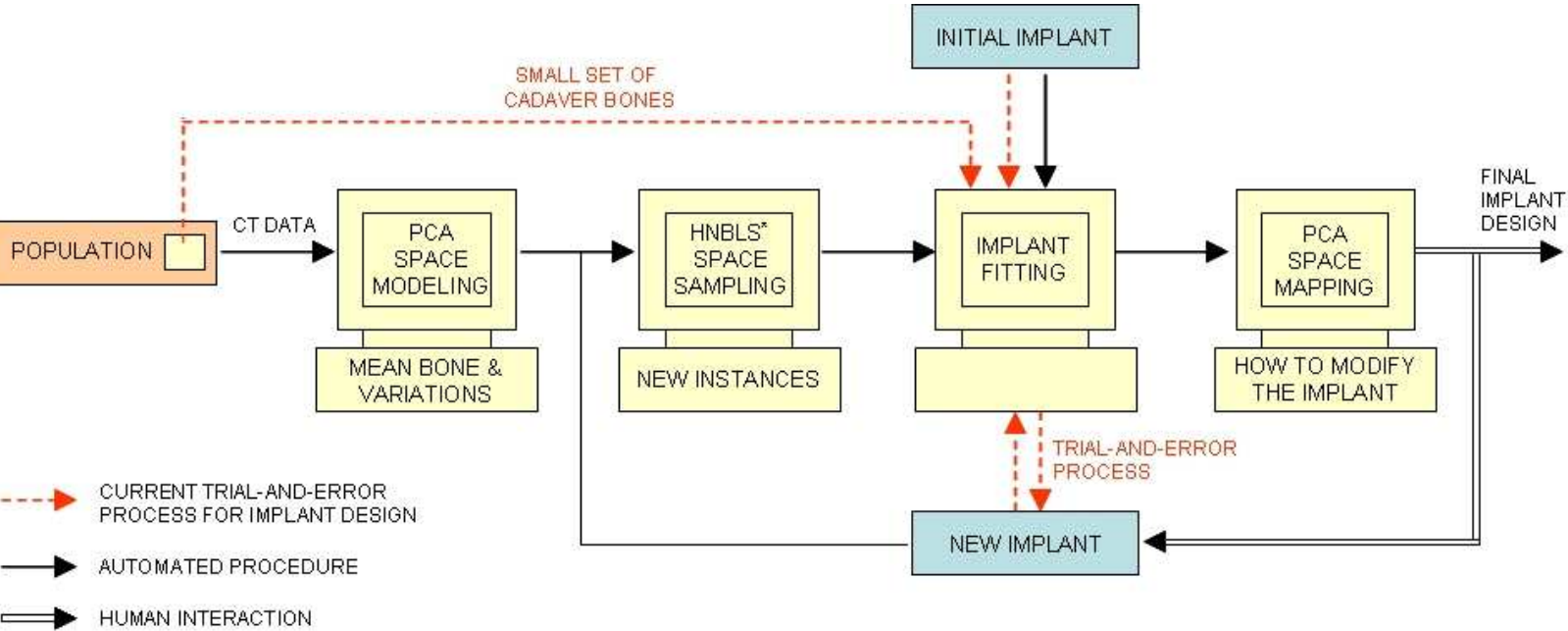


Figure13



*HNBLs – HIERARCHICAL NARROW BAND LEVEL SET

Figure14

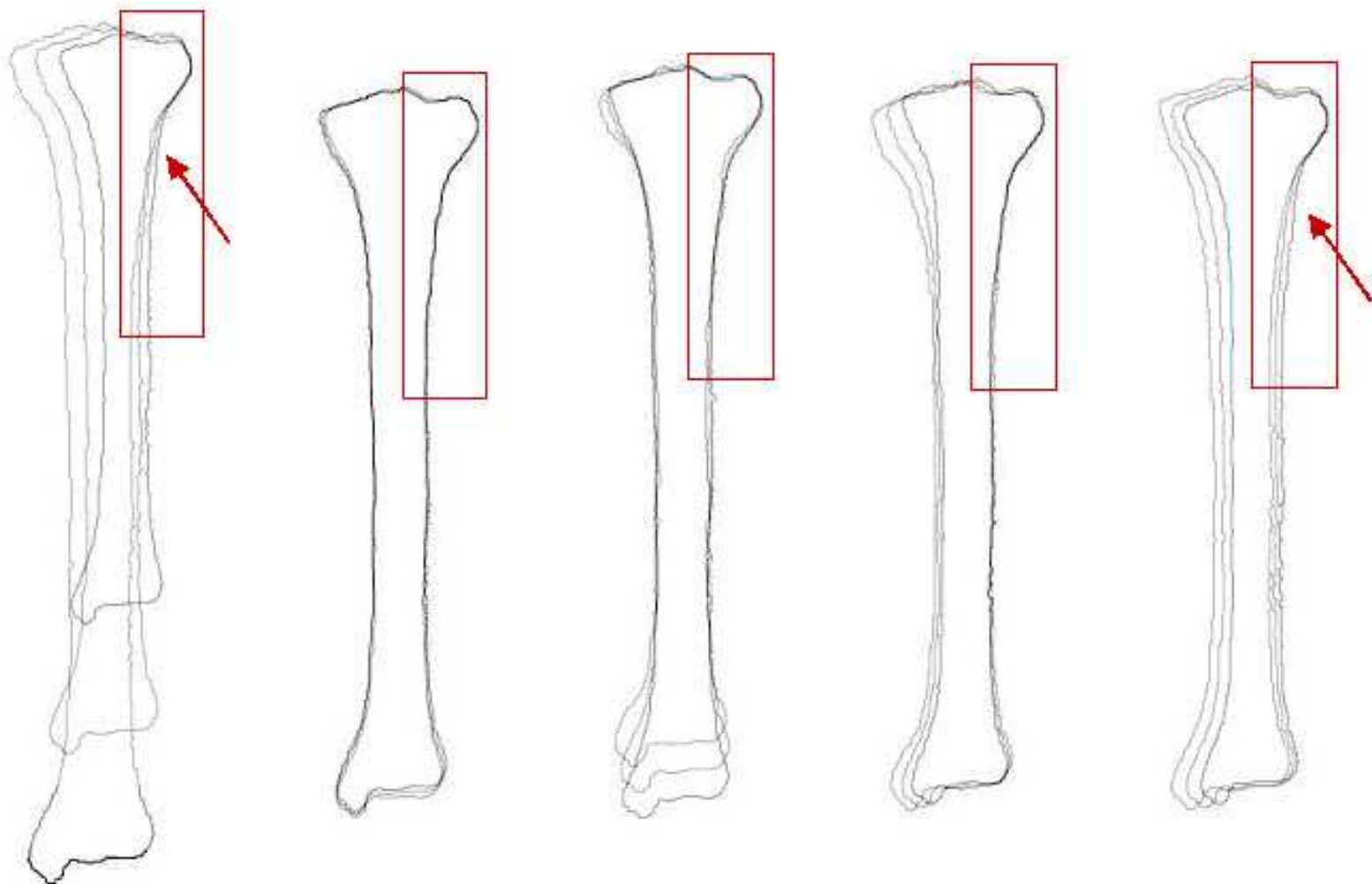


Figure15a

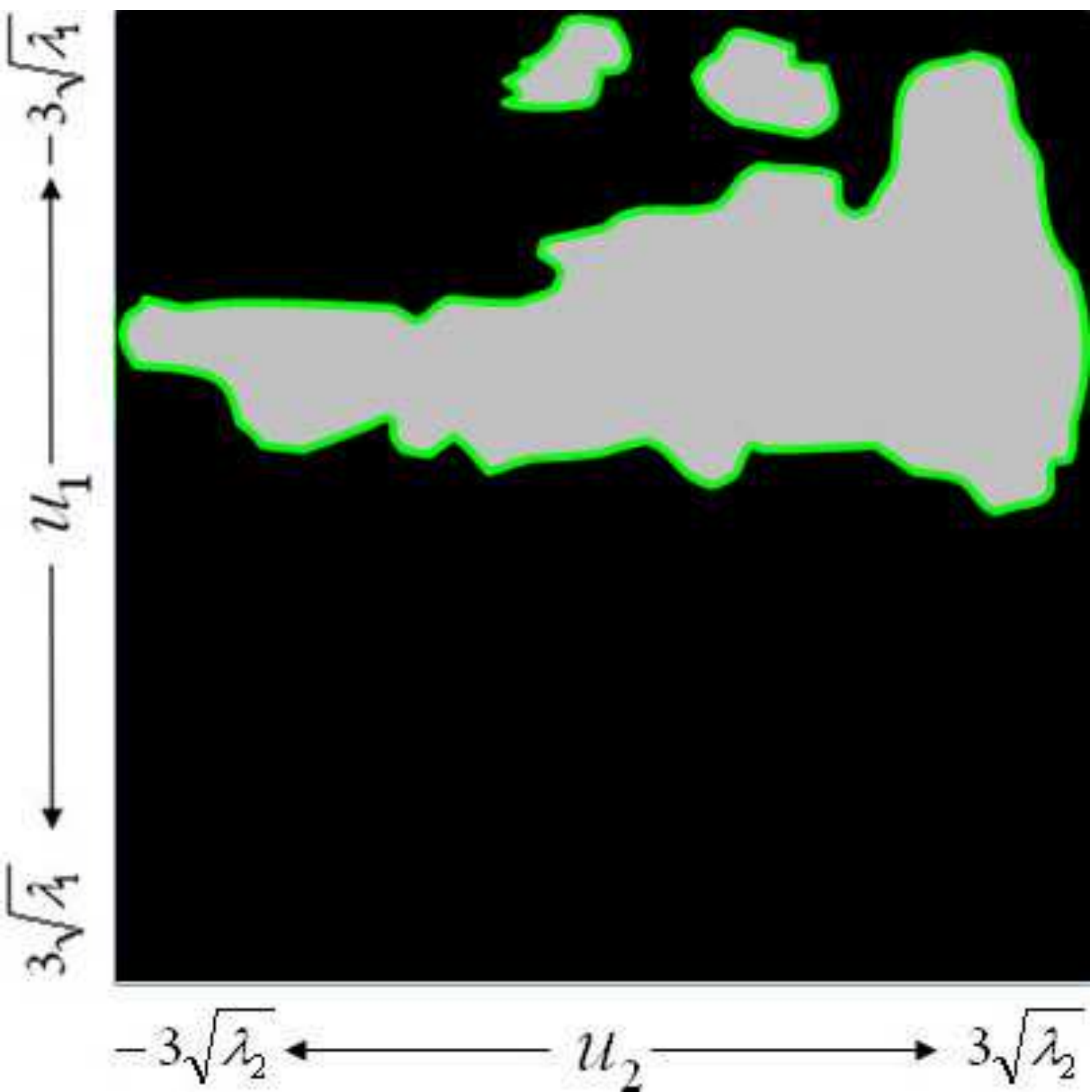


Figure15b

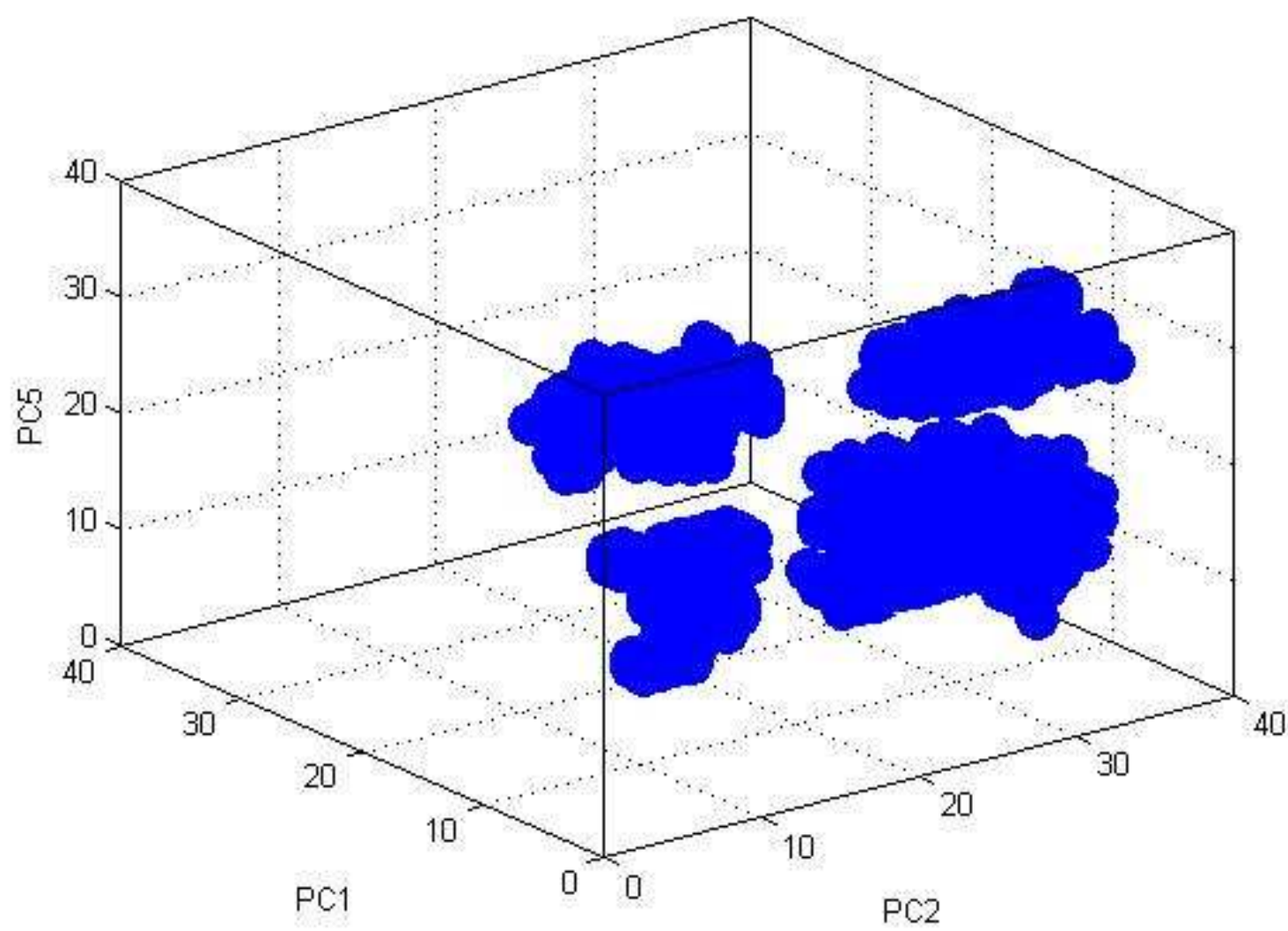


Figure15c

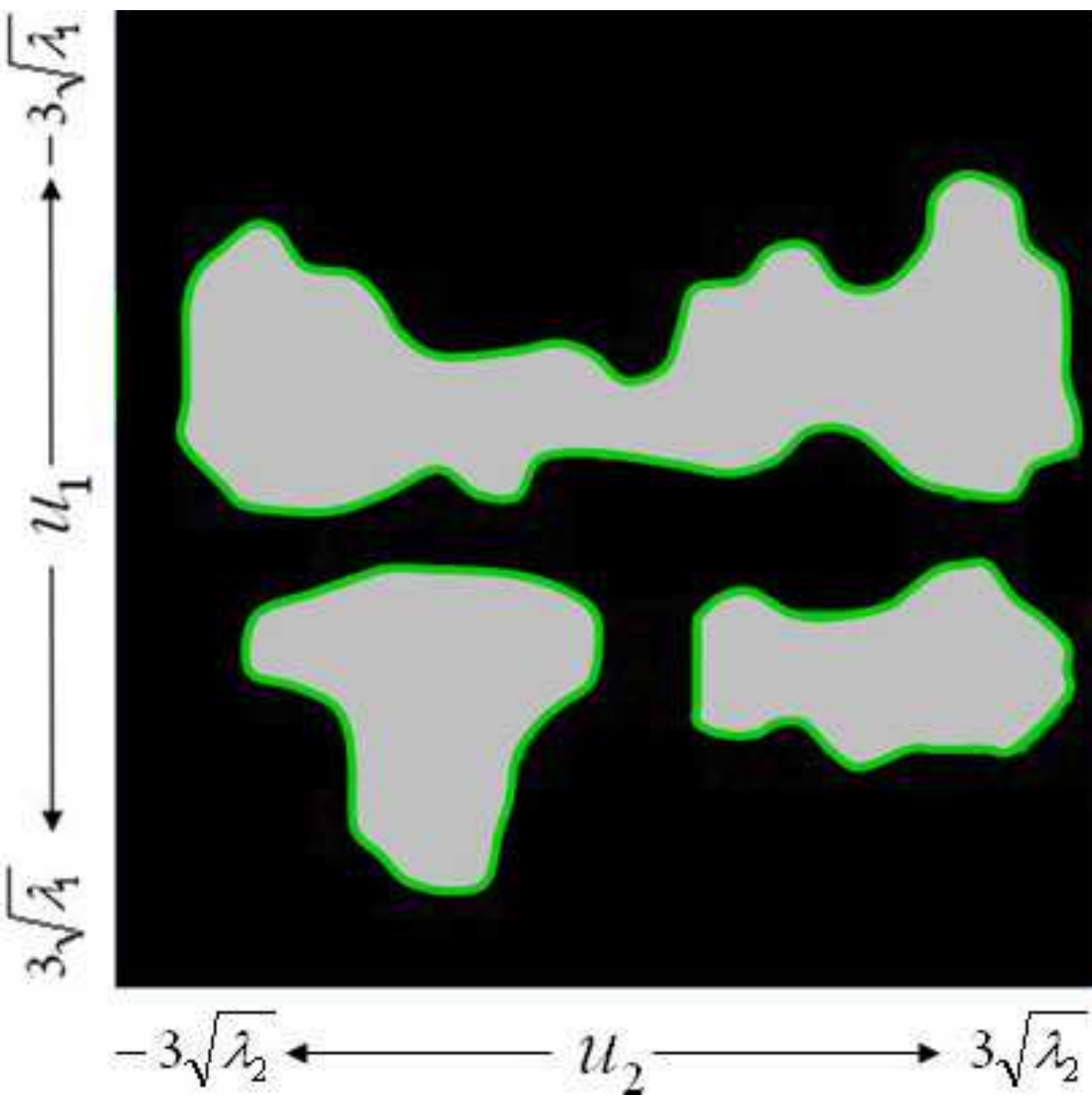


Figure15d

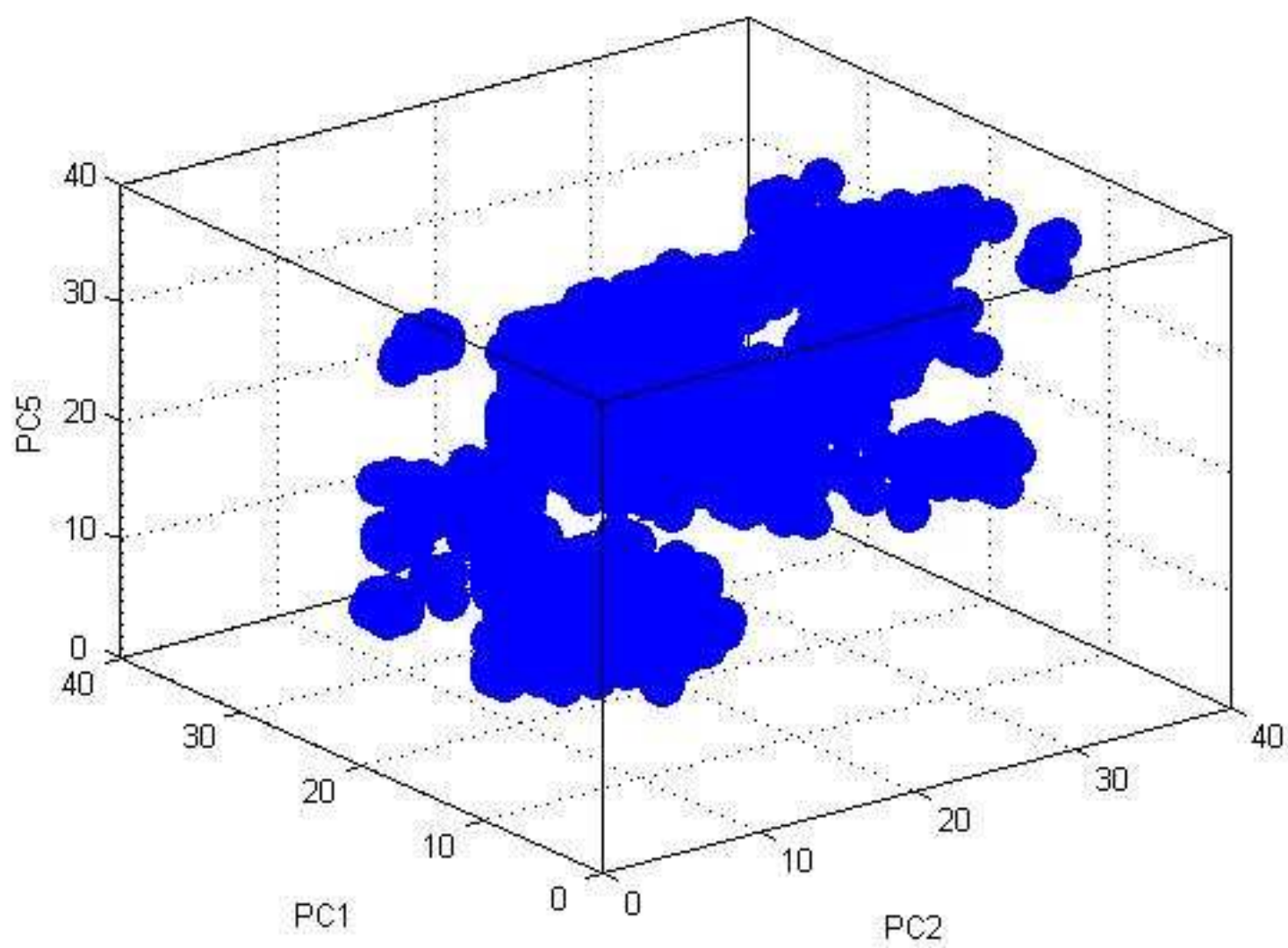


Figure16a

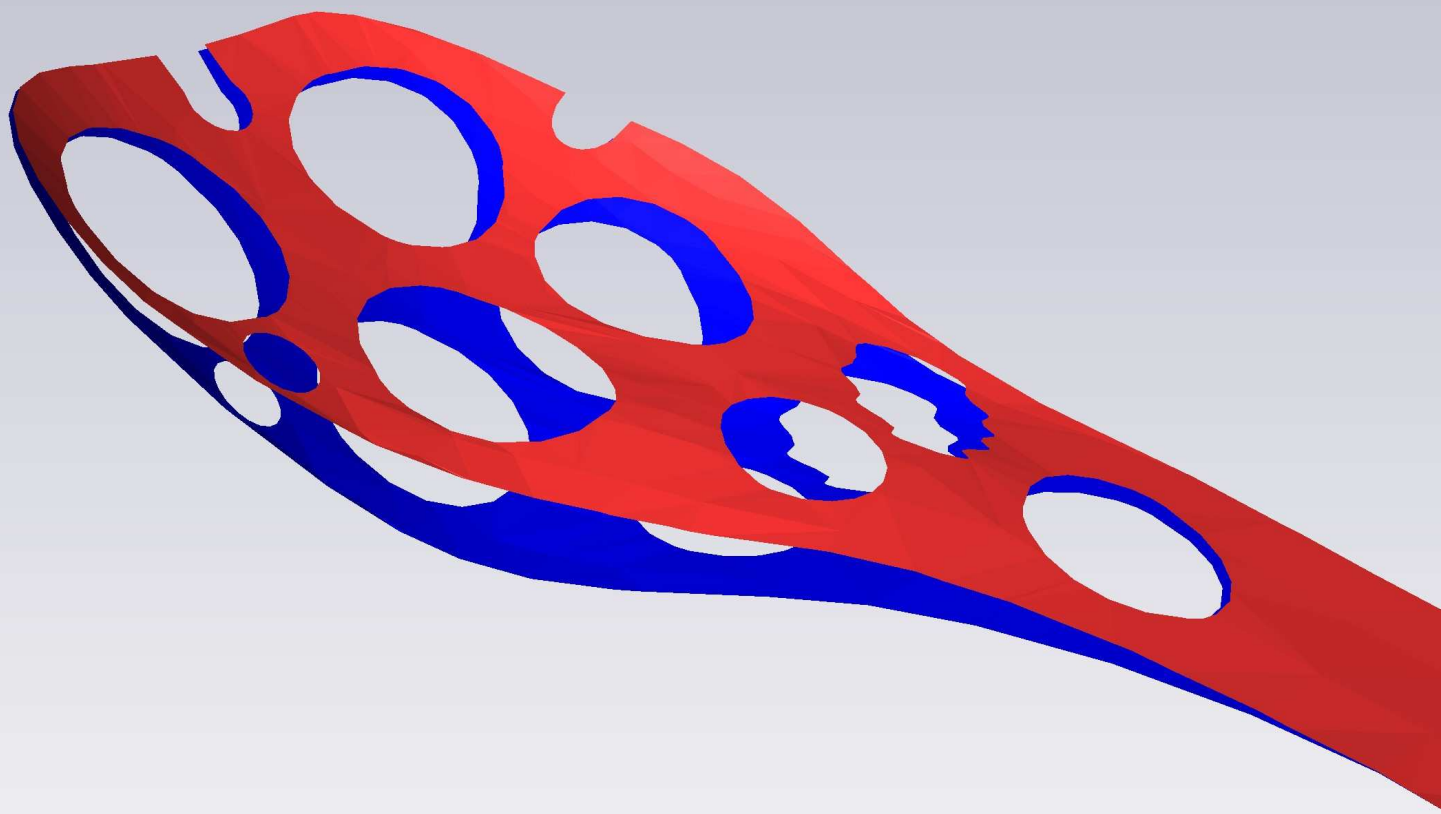


Figure16b

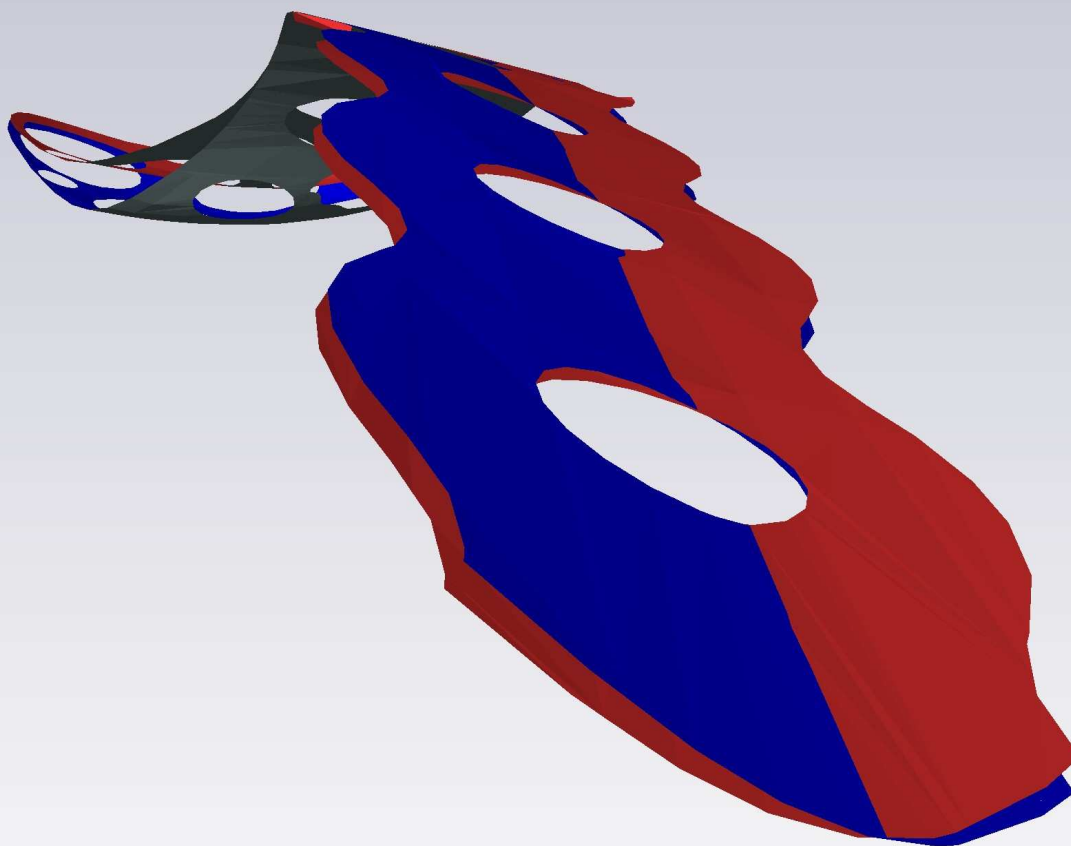


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